



BILLING CODE: 4410-09-P

**DEPARTMENT OF JUSTICE
Drug Enforcement Administration**

**Houston Maintenance Clinic
Decision and Order**

On September 30, 2016, Administrative Law Judge Charles Wm. Dorman (hereinafter, ALJ) issued Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision (hereinafter, R.D.). Only Houston Maintenance Clinic (hereinafter, Respondent) filed exceptions (hereinafter, Resp. Exceptions), and its filing was timely. Having reviewed the entire record, including Resp. Exceptions, and modified the ALJ's R.D., I adopt the modified R.D. and find that none of Resp. Exceptions has merit.

Respondent's First Exception

Respondent's first exception states that R.D. "Finding of Fact 40 should be amended to include the first sentence in . . . [Respondent's owner's] letter, GE 27[,], that states as follows[,]" "The facility has kept a systematic ongoing accurate daily dispensing record as required by title 21 C.F.R. 1304.03."¹ Resp. Exceptions, at 1. The support Respondent provided for this exception is that, "The daily dosing records . . . are required and these were kept without disruption." *Id.*

First, R.D. Finding of Fact 30, citing GE-27, already states that, "Around the time of the [2006] inspection, . . . [Respondent] kept ongoing, systematic daily dispensing records" [footnote omitted]. Thus, much of the content of the sentence that Respondent's first exception proposes is already found in Finding of Fact 30. Only the assertions that Respondent "has kept . . . accurate" daily dispensing records "as required by title 21 C.F.R. 1304.03" do not appear in

¹ Finding of Fact 40 and, presumably, Respondent's first exception concern the 2006 inspection.

Finding of Fact 30. Respondent's first exception does not mention Finding of Fact 30 and does not explain why it reiterates statements found in Finding of Fact 30.

Second, the Agency's regulation concerning exceptions requires that supporting reasons, specific citations to the evidence in the record, and applicable authorities be included with exceptions. The regulation states that, "The party shall include a statement of supporting reasons for such exceptions, together with evidence of record (including specific and complete citations of the pages of the transcript and exhibits) and citations of the authorities relied upon." 21 C.F.R. § 1316.66(a) (1979).

Respondent's first exception does not comply with the Agency's regulation because it does not "include . . . evidence of record (including specific and complete citations of the pages of the transcript and exhibits)." *Id.* Instead, it simply asserts that "daily dosing records . . . were kept without disruption." Resp. Exceptions, at 1. It does not provide support from evidence in the record that Respondent "has kept . . . accurate" daily dispensing records "as required by title 21 C.F.R. 1304.03." Thus, I find that Respondent's first exception does not comply with the Agency's regulation. 21 C.F.R. § 1316.66(a) (1979).

Third, the sentence that Respondent proposes for addition to the R.D.'s 40th Finding of Fact is taken from Respondent's written response (GE-27) to the Drug Enforcement Administration (hereinafter, DEA or Government) Letter of Admonition (GE-26) sent after the 2006 inspection. The 2006 inspection is addressed in subparagraph 2.c. of the Order to Show Cause (hereinafter, OSC). In pertinent part, the OSC alleges that Respondent failed "to maintain and keep accurate records (daily dispensing logs) for controlled substances." OSC, at 2. I am not sustaining this OSC allegation due to insufficient evidence in the record: "[T]he Government did not enter any evidence specifically showing that . . . [Respondent's] daily dispensing records

were inadequate at the time of the 2006 inspection.”² R.D., at 39. Respondent’s first exception does not mention or acknowledge that the ALJ recommended against sustaining this OSC allegation. Respondent does not explain why it proposes an exception concerning an allegation that the ALJ recommended against sustaining.

Fourth, it does not follow from the Government’s lack of proof concerning the inadequacy of Respondent’s daily dispensing records at the time of the 2006 inspection that Respondent actually kept daily dispensing records that were accurate and in compliance with Agency regulations. As already discussed, Respondent’s first exception does not cite to evidence in the record that provides a basis for me to find that Respondent did keep daily dispensing records that were accurate and in compliance with Agency regulations at the time of the 2006 inspection.

For all of the above reasons, I reject Respondent’s first exception.

Respondent’s Second Exception

Respondent’s second exception states that R.D. “Finding of Fact 87 should be amended to include the fact that the investigators’ variance computations were incorrect by at least 160,000 mgs in the methadone diskettes.”³ Resp. Exceptions, at 1. Respondent cites “Tr. 513” to support this exception.

First, Respondent’s second exception does not comply with the Agency’s exception regulation because it does not “include a statement of supporting reasons.” 21 C.F.R. § 1316.66(a) (1979). Instead, it simply advises that “Respondent believes” that “Finding of Fact

² There is evidence in the record that, “up until the time of the 2006 inspection,” Respondent “kept meticulous daily dispensing records.” R.D., at 39.

³ Finding of Fact 87 concerns the 2014 inspection.

87 should be amended.”⁴ Resp. Exceptions, at 1. I find that Respondent’s second exception also does not comply with the applicable Agency regulation. 21 C.F.R. § 1316.66(a) (1979).

Second, the only support Respondent provides for its stated “belief” that the 87th Finding of Fact “should be amended” is its citation to page 513 of the hearing transcript. Respondent does not, however, specify the particular portion of page 513 that is relevant or discuss why that material supports its second exception.

Hearing transcript page 513 concerns the cross-examination by Respondent’s counsel of one of the DEA Diversion Investigators (hereinafter, DI) assigned to the more recent inspections of Respondent. On lines 18 through 24, Respondent’s counsel elicits testimony from the DI that “[i]t looks like” there “may have been an error in . . . [the] spreadsheet” of “160,000 milligrams of methadone.” Tr. 513. This testimony appears either to refer to page 2 of GE-9, where there is a blank space in the “Total Dosage Units Received” column for “Methadone” received on June 24, 2014, or to page 1 of GE-9.⁵ I see no reference on page 513 to “variance computations,” let alone to variance computations being “incorrect by at least 160,000 mgs in the methadone diskettes” as Respondent’s second exception asserts. Thus, the hearing transcript page cited in Respondent’s second exception is not evidentiary support for Respondent’s proposed amendment to Finding of Fact 87.

Third, Respondent’s second exception concerns Respondent’s “belief” that 1,200,050 dosage units, the amount of variance in its methadone diskettes calculated by the Government during the 2014 inspection, is not accurate. Respondent does not, however, point to any

⁴ It does cite to page 513 of the hearing transcript, but it does not provide a pinpoint citation to what it considers to be the relevant material on that page.

⁵ Although not specifically addressed on page 513, other portions of the hearing transcript indicate that the number for the blank space on page 2 of GE-9 in the “Total Dosage Units Received” column for “Methadone” received on June 24, 2014 is the product of the “Quantity Received (Pkg),” (40), and the “Package Size,” (4,000).

evidence in the record stating the correct amount of variance. Even more significantly, though, Respondent's second exception clearly acknowledges that Respondent's controlled substance inventories included a variance in its methadone diskette inventory for the 2014 inspection time period.

I am sustaining the OSC allegation that the 2014 inspection found variances in Respondent's controlled substance inventories of methadone diskettes, liquid methadone, buprenorphine 2 mg tablets, and buprenorphine 8 mg tablets. R.D., at 45. As Respondent asserts that the Government's variance computations were incorrect "by at least 160,000 mgs," it is acknowledging the existence of variances. That acknowledgement supports my conclusion, concerning the 2014 inspection, that "Respondent failed to maintain complete and accurate records of controlled substances received, sold, and delivered, and that there was a variance in . . . [Respondent's] controlled substance inventory." R.D., at 45. I calculated the variance in Respondent's methadone diskette inventory based on figures that account for the apparent 160,000 mg math error. Although the recalculated variance is smaller than the figure on the first page of GE-9, it does not change my findings concerning the 2014 inspection or my decision to revoke.

For all of the above reasons, I reject Respondent's second exception.

ORDER

Pursuant to 28 C.F.R. § 0.100(b) (2018) and the authority thus vested in me by 21 U.S.C. § 824(a) (Westlaw through Pub. L. No. 115-223) in conjunction with 21 U.S.C. § 823(g)(1) (Westlaw through Pub. L. No. 115-223), I order that DEA Certificate of Registration No.

RH0208567 issued to Houston Maintenance Clinic be, and it hereby is, revoked. I further order that any pending application of Houston Maintenance Clinic for renewal or modification of its registration be, and it hereby is, denied. This Order is effective [insert Date Thirty Days From the Date of Publication in the Federal Register].

Dated: August 8, 2018.

Uttam Dhillon,
Acting Administrator.

Paul A. Dean, Esq., for the Government

Andre D'Souza, Esq., for the Respondent

RECOMMENDED RULINGS, FINDINGS OF FACT, CONCLUSIONS OF LAW, AND DECISION OF THE ADMINISTRATIVE LAW JUDGE

Charles Wm. Dorman, Administrative Law Judge. On September 10, 2015, the Drug Enforcement Administration (“DEA” or “Government”) served Houston Maintenance Clinic (“Respondent” or “HMC”) with an Order to Show Cause (“OSC”) seeking to revoke the Respondent’s DEA Certificate of Registration (“COR”), Number RH0208567. Administrative Law Judge Exhibits (“ALJ-”) 1-2. In response, the Respondent requested a hearing before an Administrative Law Judge. ALJ-3. That hearing was held in Houston, Texas on June 13 through 16, 2016. The issue currently before the Administrator is whether the DEA should revoke the Respondent’s COR, pursuant to 21 U.S.C. § 824(a), and deny any pending applications for renewal or modification of its registration, pursuant to 21 U.S.C. § 823(g)(1). The following recommendations are based on my consideration of the entire administrative record, including all of the testimony, admitted exhibits, and the oral and written arguments of counsel.

ALLEGATIONS

1. On April 17, 1997, the DEA discovered that the HMC failed to record the amount of controlled substances received, failed to keep DEA 222 Order Forms (“222 Forms”), and failed to properly maintain daily dispensing records, in violation of 21 C.F.R. §§ 1304.03, 1304.04, 1304.21, 1304.22, and 1304.24.1.⁶ ALJ-1, at 1-2. On that date, the DEA found variances in the HMC’s controlled substance inventory. ALJ-1, at 2. Subsequently, the HMC received a letter of admonition detailing its violations. ALJ-1, at 2.
2. On December 6, 1999, the DEA discovered that the HMC failed to maintain complete and accurate records of Schedule II controlled substances received and dispensed, in violation of 21 U.S.C. § 827(a)(3) and 21 C.F.R. § 1304.21(a). ALJ-1, at 2. On that date, the DEA found

⁶ As the Government notes in its Post-Hearing Brief, ALJ-27, the code sections cited in the OSC are to the current version of the C.F.R., rather than the version in effect at the time of the alleged violations. The substance of the code remains the same. For the sake of clarity and simplicity, the current version of the C.F.R. is cited throughout this Recommended Decision.

- variances in the HMC's controlled substance inventory. ALJ-1, at 2. Subsequently, the HMC entered a Memorandum of Understanding, acknowledging its violations. ALJ-1, at 2.
3. On September 8 and 11, 2006, the DEA discovered that the HMC failed to keep and maintain daily dispensing logs of controlled substances, in violation of 21 C.F.R. § 1304.21(a). ALJ-1, at 2. On that date, the DEA found variances in the HMC's controlled substance inventory. ALJ-1, at 2. Subsequently, the HMC received a letter of admonition detailing its violations. ALJ-1, at 2.
 4. On October 11 and 13, 2011, the DEA discovered that the HMC failed to provide records in a timely manner, failed to maintain complete and accurate controlled substance receipt records, failed to conduct a biennial inventory, failed to preserve 222 Forms for two years, improperly allowed an unauthorized person to sign 222 Forms, failed to execute a power of attorney to allow an alternate person to sign 222 Forms, and failed to completely and accurately complete daily dispensing logs, in violation of 21 C.F.R. §§ 1304.04(f)(1)(2), 1304.04, 1304.11(a), 1305.04, 1305.17(a), 1305.17(c), 1305.05, and 1305.24(a).⁷ ALJ-1, at 2. The HMC also failed to maintain adequate physical security of controlled substances. ALJ-1, at 2. Further, the DEA was unable to conduct an audit during the inspection because of the HMC's recordkeeping deficiencies. ALJ-1, at 2. On April 3, 2013, the HMC entered a settlement agreement with the United States based on these violations. ALJ-1, at 2. By the terms of the settlement agreement, the HMC agreed to pay a civil monetary penalty, but denied culpability or wrongdoing. ALJ-1, at 2.
 5. On October 14, 2014, the DEA discovered that the HMC failed to: maintain complete and accurate records of each controlled substance received, sold, and delivered; conduct a biennial inventory and an inventory of buprenorphine; preserve 222 Forms; indicate the date of receipt of 222 Forms; execute a power of attorney authorizing an alternate person to sign 222 Forms; and complete accurate daily dispensing logs, in violation of 21 C.F.R. §§ 1304.21(a), 1304.11(c), 1304.11(b), 1305.17(a), 1305.13(e), 1305.05, and 1304.24(a). ALJ-1, at 3. On that date, the DEA found variances in the HMC's controlled substance inventory. ALJ-1, at 3.

⁷ 21 C.F.R. § 1305.24(a) discusses maintenance of ordering records using an electronic central processing system. The facts of this case do not relate to any alleged violations dealing with ordering records maintained on an electronic central processing system. Therefore, the Government's allegation that the Respondent's conduct on October 11 and 13, 2011, and October 14, 2014, violated 21 C.F.R. § 1305.24(a) is **NOT SUSTAINED**.

STIPULATIONS OF FACT

The Government and the Respondent stipulated to the following facts:

1. Respondent is registered with the DEA as a narcotic treatment program in Schedules II and III under DEA Registration RH0208567 at 4608 Main Street, Houston, Texas 77002.
2. DEA Registration Number RH0208567 expires by its terms on October 31, 2016.

WITNESSES

The Government presented its case-in-chief through the testimony of six witnesses. First, the Government called a DEA Unit Chief (“Unit Chief”). Tr. 27-84. The Unit Chief previously worked in the DEA’s Houston Division Office for approximately eight years. Tr. 28. Along with two other DEA investigators, the Unit Chief participated in the DEA’s inspection of the HMC in 1999. Tr. 28. At that time, the Unit Chief was a trainee, and the 1999 inspection was one of the first methadone clinic inspections in which she had participated. Tr. 28, 31. The Unit Chief assisted with the 1999 inspection by counting the HMC’s on-hand inventory and by helping with the controlled substances audit. Tr. 29, 38-39. The Unit Chief also recalled meeting with Dr. Ozumba during that inspection, but was unsure if anyone else was present during that meeting. Tr. 29-30. The Unit Chief added up purchase records, dispensing records, and the closing inventory for the audit’s computation chart, Government’s Exhibit (“GE-”) 30. Tr. 80-82. Through the Unit Chief’s testimony, the Government authenticated and successfully offered into evidence GE-28-30 and 32. *See* Tr. 27-84. I find all of these exhibits to be accurate, authentic, and meriting credibility.

While I find the Unit Chief to be a generally credible witness, several key factors detract from her overall credibility. First, at the time of the 1999 inspection, the Unit Chief was a trainee, who had not yet attended the DEA academy. Tr. 28. Second, during her testimony, I sensed that she was testifying based upon her experience of how DEA conducts inspections, not on her specific recollection of what happened during the inspection in 1999. I even addressed that concern on the record. Tr. 40-41, 81. Third, she testified that Dr. Ozumba was present during the inspection, but she was not sure if anyone else representing the Respondent was there. Tr. 29-30. She recalls Dr. Ozumba, in part, because he had a “very deep voice,” and she

attempted to mimic his voice during her testimony. Tr. 47. She also testified that Dr. Ozumba signed the Notice of Inspection in 1999. Tr. 30. Dr. Ozumba, however, did not sign the Notice of Inspection; it was signed by another employee of the HMC who was there. Tr. 47; *see also* GE-28. Furthermore, when Dr. Ozumba testified, given the Unit Chief's earlier testimony and mimicking, I was struck by the fact that Dr. Ozumba does not have a deep voice at all. Fourth, the Unit Chief's testimony was internally inconsistent concerning whether a closing interview was conducted. At first, she testified that she participated in a closing interview with the owners of the clinic. Tr. 38-39. Later, the Unit Chief testified that she could not recall if a closing inventory had been conducted. Tr. 78. Finally, this inspection occurred over seventeen years ago. While I find that the Unit Chief's testimony generally was forthright and honest, where her testimony directly conflicts with the testimony of other witnesses, I give the Unit Chief's testimony less weight.

Second, the Government presented the testimony of Latoya Latrese McSwain, L.P.N. ("McSwain"). Tr. 85-147. McSwain was employed by the HMC as a dosing nurse from January 2014 through January 2015. Tr. 86, 102. McSwain was familiar with the manner in which controlled substances were inventoried at the HMC. Tr. 112. McSwain signed and initialed parts of the HMC's daily dispensing record. *See* Respondent's Exhibit ("RE-") A, at 85, 91. Along with the HMC's receptionist, McSwain was at the clinic when DEA investigators conducted an inspection in 2014. Tr. 87. Before Dr. Ozumba arrived at the HMC during that inspection, the DEA Diversion Investigator Case Agent ("Case Agent") spoke with McSwain. Tr. 92, 110. During the inspection, McSwain helped thoroughly search the HMC for the documents requested by DEA. Tr. 89-90. I find McSwain's testimony to be detailed, thorough, honest, and internally consistent. Therefore, with one exception, I merit her testimony as credible in this Recommended Decision. I do not credit her testimony concerning the time the DEA investigators arrived to conduct the inspection on October 14, 2014.

Third, the Government presented the testimony of Natalie Benjamin Farr Franks ("Franks"). Tr. 148-79. Franks worked for the HMC as a dispensing nurse from February 2010 through June 2012, except for a six-month period in which Franks took maternity leave. Tr. 149-50. As a dispensing nurse, Franks handled recordkeeping, administered medication, and inventoried the HMC's controlled substances. Tr. 151-52. I find Franks' testimony to be

detailed, thorough, honest, and internally consistent. Therefore, I merit her testimony as credible in this Recommended Decision.

Fourth, the Government presented the testimony of a DEA Group Supervisor (“Group Supervisor”). Tr. 187-264. The Group Supervisor has worked for the DEA for about 10 years. Tr. 188. In January 2005, the Group Supervisor began working as a diversion investigator at the DEA’s Houston office. Tr. 188. On September 8, 2006, the Group Supervisor participated in a scheduled inspection of the HMC. Tr. 192. During that inspection, the Group Supervisor observed the physical audit of the HMC’s controlled substances and provided calculations to create a closing inventory, GE-23. Tr. 204-06. Through the Group Supervisor’s testimony, the Government authenticated and successfully offered into evidence GE-22-26. *See* Tr. 187-264. I find all of these exhibits to be accurate, authentic, and meriting credibility. I also find the Group Supervisor’s testimony to be detailed, thorough, honest, and internally consistent. Therefore, I merit her testimony as credible in this Recommended Decision.

Fifth, the Government presented the testimony of the Case Agent. Tr. 265-610. The Case Agent has worked for the DEA as a diversion investigator for six years. Tr. 266. The Case Agent investigates DEA registrants to verify their compliance with the Controlled Substances Act, and she has participated in over 100 scheduled investigations. Tr. 266-67. The Case Agent formerly worked in the DEA’s Houston office, and she currently works in the Miami office. Tr. 266. The Case Agent participated in the DEA’s October 2011 and October 2014 scheduled inspections of the HMC. Tr. 271-72. Through the Case Agent’s testimony, the Government authenticated and successfully offered into evidence GE-3-6, 8-21, 31, and 33-37. *See* Tr. 265-610. I find all of these exhibits to be accurate, authentic, and meriting credibility. There is credible evidence of record that the Case Agent found dealing with the Ozumba’s to be frustrating and that she was brusque in her dealing with them. There is also credible evidence that the Case Agent is a professional and well-trained DEA investigator. Therefore, I do not find that her frustration or brusqueness adversely impacts her credibility in this case. I find the Case Agent’s testimony to be detailed, thorough, honest, and internally consistent. Therefore, I merit her testimony as credible in this Recommended Decision.

Sixth, the Government presented the testimony of Cecilia Ozumba (“Mrs. Ozumba”). Tr. 643-938. The Respondent also elicited direct examination testimony from Mrs. Ozumba. Tr. 813. Mrs. Ozumba was educated and trained in clinical psychology and chemical

dependence counseling; she is not educated and trained as a regulatory specialist. Tr. 814, 817, 821, 828. Through Mrs. Ozumba's testimony, the Government authenticated and successfully offered into evidence GE-7 and 27. *See* Tr. 643-938. Additionally, through Mrs. Ozumba's testimony, the Respondent authenticated and successfully offered into evidence RE-A, B, pages one through four of RE-C, RE-E, G, H, X, Z, and BB.

During her testimony, Mrs. Ozumba seemed confused, had difficulty recalling pertinent information, and at times was evasive, particularly during the initial direct examination by Government counsel. For example, she was confused concerning: who had signed the DEA application for the HMC; the 1999 inspection; the sequence of the 2011 inspection; and how RE-C had been created. Tr. 646, 685-89, 750, 787-99. Confusion persisted throughout her first day of testimony, with examples too numerous to cite. She was not sure of: the number of times the HMC had been inspected by DEA; when the HMC started using buprenorphine; when RE-BB was provided to the Government; what documents she brought with her to the 2011 informal hearing; and whether the DEA investigators took documents away from the HMC during the 2011 inspection. Tr. 670, 672, 685-89, 716, 738-39, 754-55. I also found her testimony evasive about the training she received concerning DEA regulations. Tr. 663-69. At times, her testimony was internally inconsistent, such as when she testified that she was not sure if the DEA inspectors removed documents from the HMC during the 2011 inspection, and then later testified that they did, and when testifying that Dr. Ozumba was both there and not there during the 2011 inspection. Tr. 754-56. In addition, Mrs. Ozumba frequently had trouble finding her place on exhibits when being questioned by counsel; in fact, to speed the process along, I highlighted one of the exhibits for her. Tr. 648, 680, 707-08, 801-03 (indication of "pause"), 833-34, 875, 896, 919. While these factors detract from Mrs. Ozumba's overall credibility as a witness, I found her to be truthful concerning her own medical issues, the recordkeeping procedures she had in place in the HMC, and her belief that the deficiencies related to the 1997, 1999, and 2006 inspections had been "resolved." Where her testimony conflicts with the testimony of other witnesses, I give her testimony less weight.

The Respondent presented its case through the testimony of four witnesses, including Mrs. Ozumba. The Respondent presented the testimony of a second witness, Sharon Bultron,

R.N. (“Bultron”).⁸ Tr. 612-43. Bultron has been a nurse for 30 years and began working for the HMC in June 2006; she still currently works for the HMC on a part-time basis. Tr. 613-14, 623. Bultron was present during the 2006 DEA inspection. Tr. 629. Bultron testified that she did not participate in the 2006 inventory. Tr. 631. When she examined GE-23, however, she concluded that she had assisted with the inventory. Tr. 634-35; *see* GE-23.⁹ I find Bultron’s testimony to be detailed, thorough, honest, and internally consistent. Therefore, I merit her testimony as credible in this Recommended Decision.

Third, the Respondent presented the testimony of William “Rusty” Garnett (“Garnett”). Tr. 947-1007. Garnett testified that he currently works as a “glorified administrator” for the HMC; specifically, he runs the front desk and has contact with patients and vendors. Tr. 948. Garnett worked for the HMC from May 2012 through May 2013, and returned to work there in December 2015. Tr. 949-50. Garnett has always worked for the HMC as a part-time employee, working six days a week. Tr. 973. Garnett was not present at the HMC during any of the DEA’s inspections. Tr. 974. Garnett personally receives daily dispensing numbers from the dispensing nurses and enters those numbers into a digital perpetual inventory. Tr. 949. Garnett testified that he created RE-X, a document that Mrs. Ozumba claims to have created in 2006. Tr. 935, 963, 1004. I find Garnett’s testimony to be detailed, thorough, honest, and internally consistent. Therefore, I merit his testimony as credible in this Recommended Decision.

Fourth, the Respondent presented the testimony of Dr. Amos Ozumba (“Dr. Ozumba”). Tr. 1008-36. Dr. Ozumba is a psychotherapist and was the original DEA registrant for the HMC. Tr. 1008-09. Dr. Ozumba’s testimony was at times confusing, internally inconsistent, and inconsistent with the testimony of other witnesses. For example, Dr. Ozumba testified about the DEA’s 2011 inspection, first saying that he was called by McSwain, but the Respondent’s counsel pointed out that Franks, not McSwain, was the dispensing nurse at the HMC at the time. Tr. 1009-10. In addition, despite several attempts by Respondent’s counsel to clarify whether Dr. Ozumba was testifying about the 2011 or 2014 inspection, Dr. Ozumba erroneously remained firm that he was testifying about the 2011 inspection when, in reality, he described details from the 2014 inspection. Tr. 1009-12. Further, Dr. Ozumba testified both that he explained to the investigators that his wife was sick, that she was present for the inspection, and,

⁸ With the consent of both parties, the testimony of the Respondent’s witness, Sharon Bultron, was taken out of order at the Respondent’s request. Tr. 612.

⁹ GE-23 bears Bultron’s signature and reflects that Bultron took the inventory during the 2006 inspection.

at a later point, that he could not recall if Mrs. Ozumba was present. Tr. 1010, 1012, 1027. Dr. Ozumba also testified about what the DEA inspectors did after he left the HMC. Tr. 1012. For these reasons, and for further reasons discussed *infra*, with one exception, I do not merit Dr. Ozumba's testimony as credible where it conflicts with the testimony of other witnesses. The one exception concerns his testimony that the closing inventory had been taken prior to his arrival at the HMC on October 14, 2014. Tr. 1017-18; *see* GE-11 (documenting that the closing inventory was taken at 9:15 a.m.).

Following the Respondent's case-in-chief, the Government presented the testimony of two rebuttal witnesses. First, the Government presented the testimony of a DEA diversion investigator ("DI"). Tr. 1038-52. The DI has worked in the DEA's Houston office for the past five years. Tr. 1039. The DI participated in the DEA's inspections of the HMC in 2011 and 2014. Tr. 1039. I find the DI's testimony to be detailed, thorough, honest, and internally consistent. Therefore, I merit her testimony as credible in this Recommended Decision, except for the following issues: whether McSwain was still dosing patients when the DEA investigators arrived; and whether a closing inventory was taken prior to Dr. Ozumba's arrival at the clinic on October 14, 2014. *See* GE-11 (documenting that the closing inventory was taken at 9:15 a.m.).

Second, the Government presented the testimony of Assistant United States Attorney ("AUSA") Jill Venezia ("Venezia"). Tr. 1053-71. Venezia has been an AUSA in Houston since 1997. Tr. 1054. In 2013, Venezia handled a case against the Respondent on behalf of the United States Attorney's Office. Tr. 1054-55. That case concerned the HMC's alleged recordkeeping violations discovered during the 2011 inspection. Tr. 1055. I find Venezia's testimony to be detailed, thorough, honest, and internally consistent. Therefore, I merit her testimony as credible in this Recommended Decision.

The Respondent attempted to introduce the testimony of a rebuttal witness. That witness had attended every session of the hearing. I excluded the witness, citing the sequestration order that I issued pursuant to the Respondent's request at the beginning of the hearing. Tr. 1072-73.

The factual findings below are based on a preponderance of the evidence, including the detailed, credible, and competent testimony of the aforementioned witnesses, the exhibits entered into evidence, and the record before me.

FACTUAL FINDINGS

I. Background on the Respondent

1. The HMC is a narcotic treatment program in Houston, Texas. *See* Stipulation (“Stip.”) 1; GE-1. The HMC opened in 1995 or 1996. Tr. 824. When the HMC opened, it was a small clinic that participated in client referral for job retraining. Tr. 825-26. The HMC also provided counseling in life skills, stress management, and relapse prevention. Tr. 825-26. When the HMC first began its operations, Mrs. Ozumba did not run the clinic. Tr. 824.
2. The HMC employed a medical director, a counselor, dispensing nurses, and an office manager. Tr. 826-27. The HMC dispensed liquid methadone¹⁰ and methadone diskettes to its patients.¹¹ *See* Tr. 157. The HMC also dispensed some buprenorphine.¹² Tr. 117.
3. The HMC’s dosing hours were from 5:30 a.m. to 9:30 a.m., and the clinic closed at 10:00 a.m. Tr. 151, 763-64; *cf.* Tr. 87. The clinic, however, remained open for counseling and by appointment until 4:00 p.m. Tr. 763-64.
4. The HMC has consistently followed the same general recordkeeping procedures since the 1990s. Tr. 845-46. The dispensing nurse inventoried the controlled substances the HMC had on hand each morning. Tr. 626, 844-45. The nurse then filled out the Respondent’s dispensing log during the day and, at the end of the dispensing hours, the nurse tallied the log. Tr. 627-28, 843. The nurse also inventoried the controlled substances in the HMC’s controlled substances safe. Tr. 640, 843. The physical count of the controlled substances had to match the calculated inventory count. Tr. 173, 444-45, 843-45. The daily dosing records were kept in spiral binders. Tr. 841.
5. The HMC stored its methadone diskettes and liquid methadone in a safe with a combination lock. Tr. 175. This safe was in a room that required a key for entry. Tr. 175-76. An alarm system was connected to the safe. Tr. 175, 177.

¹⁰ Liquid methadone is also referred to as LAAM. Tr. 30, 79-80.

¹¹ Methadone is a Schedule II controlled substance. 21 C.F.R. § 1308.12(c)(15).

¹² Buprenorphine is also known as Suboxone and is an agonist-antagonist medication used in opioid treatment. Tr. 117. Substances containing buprenorphine are classified in Schedule III. 21 C.F.R. § 1308.13(e)(2)(i).

II. Background on DEA Inspections

6. A DEA group supervisor schedules inspections and audits of registrants. Tr. 190. Scheduled inspections are unannounced because the DEA expects registrants to always comply with the Controlled Substances Act and its implementing regulations, and the registrant's records are always supposed to be readily retrievable. Tr. 51, 193. Inspections are conducted during normal working hours. Tr. 51, 193.
7. DEA inspections of narcotic treatment programs generally follow the same basic format as inspections of other registrants. Tr. 191. At the beginning of a routine inspection, DEA investigators ask the registrant's representative to sign a notice of inspection. Tr. 51, 268. A notice of inspection outlines the registrant's rights and discusses the DEA's authority to inspect the registrant, and normally is accompanied by an explanation of what the DEA will do during the inspection. GE-28; Tr. 30.
8. The DEA investigators then conduct interviews to determine how the registrant's business runs and its policies and practices. Tr. 268. The investigators determine who has access to the registrant's controlled substances. Tr. 268.
9. During an inspection, registrants are asked to produce their controlled substance records, such as their biennial inventory, purchase records, dispensing records, and loss or theft reports. Tr. 194, 268. Inspections are normally done on-site, but, if the DEA takes a registrant's records off-site, the DEA provides the registrant with a receipt for the records taken. Tr. 241.
10. The inspection starts with DEA investigators obtaining the registrant's biennial audit or any physical inventory taken during the audit period; this audit or inventory is used by the DEA as a beginning inventory. Tr. 195. The DEA will then add the registrant's purchases to the inventory. Tr. 195. The total of these figures is the amount of controlled substances for which the registrant is accountable. Tr. 195.
11. The DEA then conducts a closing inventory on the day of the inspection. Tr. 195, 268. Distributions, losses, or thefts are added to the closing inventory count. Tr. 195. This combined total is the amount of controlled substances for which the registrant can account. Tr. 195.

12. If there is a difference between the controlled substances that a registrant is accountable for and the controlled substances that a registrant can account for, the DEA reviews its audit and calculations to verify that the audit was done correctly. Tr. 195-96. When a team of DEA investigators conducts an audit, all of the investigators count and check their counts against each other. Tr. 80-81, 196. If, upon further review, a difference (or “variance”) still exists, the registrant is given an opportunity to explain the difference. Tr. 196.
13. It is more difficult to obtain an accurate measurement of liquid methadone than methadone tablets. Tr. 63. Liquid methadone bottles may also be overfilled by their manufacturers. Tr. 221, 223, 256-57.¹³ A small statistical variance is expected in measurements of liquid methadone. Tr. 63, 220-21.
14. During an inspection, the DEA also evaluates the registrant’s security system. Tr. 194, 268-69. To do so, a member of the DEA’s inspection team will speak on the phone with the registrant’s security company while the registrant’s security system is intentionally breached to ensure that the security company receives signals triggered by the breach. Tr. 194.
15. At the end of an inspection, investigators normally conduct a closing discussion with the registrant to address the results of the inspection. Tr. 269; *see* Tr. 670-71 (acknowledging that after three of the DEA inspections involved in this case, the DEA discussed the results of the inspection with Mrs. Ozumba).

III. The 1997 Inspection

16. The DEA inspected the HMC on April 17, 1997. GE-33;¹⁴ *see* Tr. 401-02. Mrs. Ozumba signed the Notice of Inspection at that time. GE-33; Tr. 398-401.
17. Government’s Exhibit 34 is a copy of the closing inventory from the 1997 inspection. Government’s Exhibit 35 is a copy of the computation chart used during the inspection.
18. DEA investigators found that the HMC had a shortage of 16,144 mg of methadone tablets (a 1% difference) and a shortage of 411 mg/mL of liquid methadone (a 7% difference). GE-35; *see* GE-34 (showing that the Respondent had 249,975 mg of methadone tablets and 100 mg of liquid methadone on hand at the time of the inspection).

¹³ Liquid methadone bottles are not translucent. RE-Q.

¹⁴ In this case, exhibits more than 10 years old were obtained from archival storage. Tr. 398-401, 405.

19. On May 1, 1997, the DEA sent a letter of admonition to Mrs. Ozumba. GE-36; Tr. 404-05.
- The letter stated that the HMC failed “to maintain complete and accurate records of controlled substances Result[ing] in a variance of -16,144 (-1%) Methadone and -411 (-7%) LAAM.” GE-36. The letter directed Mrs. Ozumba to advise the DEA about what “specific steps [she] will take to correct the violations.” GE-36.
20. On May 21, 1997, Mrs. Ozumba wrote a letter to the DEA to identify corrective measures she implemented to rectify the problems identified in the 1997 inspection. GE-37; Tr. 407-09, 675-78.
21. Mrs. Ozumba accepts responsibility for the variances discovered in the 1997 inspection. Tr. 685, 687, 693, 929.

IV. The 1999 Inspection

22. On December 6, 1999, at around 10:00 a.m., the DEA inspected the HMC. *See* GE-28, 29; Tr. 48. At the beginning of the 1999 inspection, Emmanuel Uchem (“Mr. Uchem”), the HMC’s facility manager, signed a Notice of Inspection.¹⁵ Tr. 32, 47, 52, 72; *see* GE-28; *see also* GE-32, at 1 (identifying Mr. Uchem as the Respondent’s facility manager). Generally, a facility manager has access to all documents needed to conduct a DEA audit. Tr. 53-54.
23. After Mr. Uchem signed the Notice of Inspection, the DEA inventoried the HMC’s liquid methadone and methadone diskettes. Tr. 30. Government’s Exhibit 29 is a copy of the closing inventory. Tr. 33. Government’s Exhibit 30 is a copy of the computation chart used by the investigators during the inspection. Tr. 36-37.
24. DEA investigators found that the Respondent had an overage of 100,810¹⁶ mg of methadone diskettes, and a shortage of 2,591 mg of liquid methadone. GE-30; Tr. 37, 40.¹⁷ The Unit

¹⁵ The Unit Chief’s testimony that Dr. Ozumba signed the Notice of Inspection undermines her credibility. Tr. 30.

¹⁶ The Unit Chief testified that the quantity of methadone diskettes on GE-29 should have been 641,740, rather than 641,750, which would have resulted in an overage of 100,800 mg of methadone. GE-29-30; Tr. 55-59. Upon closer examination of the exhibit, however, the 641,750 figure is correct. The error occurred in the “Containers X Contents” column concerning the methadone diskettes, where the investigators added 340 to 1410, and entered 1740 as the sum. Simple addition reveals the correct total to be 1750. Thus, the totals in the “Containers X Contents” column of GE-29 would be 624,000 + 16,000 + 1750, which equals 641,750.

¹⁷ Column 5 of GE-30 represents the controlled substances the HMC had on hand when the DEA conducted the inspection. Tr. 37, 40. This number is taken from the column on GE-29 labelled “Quantity.” GE-29. The “Quantity” column of GE-29 was determined by multiplying the number of controlled substances the Respondent had on hand by the strength of the controlled substances. Tr. 55. Column 6 of GE-30 was calculated using the

Chief recalled that the Respondent had an overage of one product and a deficit of the other, but she could not recall which was which. Tr. 30-31.

25. Throughout the 1999 inspection, the employees of the HMC were cooperative with the DEA investigators. Tr. 54.
26. It is unclear whether the DEA investigators conducted a closing interview following the 1999 inspection. *Compare* Tr. 39 (stating that the Unit Chief helped conduct a closing interview, wherein the DEA discussed variances with the Respondent), *and* Tr. 74 (stating that there was a closing interview after the inspection), *with* Tr. 78 (stating that the Unit Chief was unsure whether the DEA conducted a closing interview after the inspection).
27. On December 15, 1999, the DEA issued a Notice of Hearing to the HMC, which informed the HMC that it would be the subject of a hearing concerning its failure to “maintain accurate records resulting in the following discrepancies: Methadone Diskets 40 mg +100,810 mg[,] + 3.77%[,] LAAM 10 mg/ml -2,591mg[,] -3.01%.” GE-31; *see* Tr. 398-401, 411-13.
28. On March 6, 2000, Mrs. Ozumba signed a Memorandum of Understanding (“MOU”) on the HMC’s behalf. GE-32; Tr. 65. The MOU cited the HMC for its failure to maintain a complete and accurate record of Schedule II controlled substances received and distributed. GE-32, at 1. The MOU did not mention any variances found during the December 1999 inspection. Tr. 68, 875; *see* GE-32. In the MOU, the HMC agreed to “maintain a complete and accurate record of all Schedule II controlled substances received and distributed as required by 21 U.S.C. § 827(a)(3) and 21 C.F.R. § 1304.21(a).” GE-32, at 2.
29. Mrs. Ozumba’s acceptance of responsibility for the variances discovered in 1999 is unclear. Mrs. Ozumba believed that every variance discovered after the 1997 inspection had been resolved. Tr. 694. While Mrs. Ozumba accepted responsibility for the variance found in 1999, she also denied responsibility for it. *See* Tr. 685, 689. Mrs. Ozumba specifically denied having a variance of 100,810 diskettes in 1999, stating she has never had a variance that large. Tr. 696-97; *see* GE-30. Mrs. Ozumba also testified that she believed the 1999 variances had been resolved by the MOU. Tr. 697-98.

Respondent’s controlled substance purchases and dispensing logs. Tr. 40. Column 8 is the variance amount, which represents the difference between Column 4 and Column 7. GE-30; Tr. 82.

V. The 2006 Inspection

30. Prior to the 2006 inspection, at the start of every day, Bultron inventoried the controlled substances at the HMC. Tr. 626. At the end of each day, she tallied up what she had dispensed, subtracted that from her starting inventory, and conducted a closing inventory. Tr. 627-28. Around the time of the inspection, the HMC kept ongoing,¹⁸ systematic daily dispensing records. GE-27; Tr. 878. At the time of the 2006 inspection, all of the HMC's records were paper files. Tr. 623.
31. On September 8, 2006, the DEA conducted a scheduled inspection of the HMC. Tr. 192, 198. Mrs. Ozumba signed a Notice of Inspection at 9:55 a.m. that day. GE-22; Tr. 200-01. The employees of the HMC cooperated with the DEA investigators during this inspection. Tr. 630-31. Likewise, the DEA investigators acted professionally. Tr. 634.
32. During this inspection, the HMC had an adequate¹⁹ biennial inventory. Tr. 255.
33. The HMC only provided DEA investigators with one 222 Form, which was dated June 13, 2006. Tr. 202-03; *see* GE-25.
34. The DEA inventoried the HMC's liquid methadone and methadone diskettes. GE-23; Tr. 205, 219-20. Government's Exhibit 23 is a copy of the closing inventory. Tr. 205. Government's Exhibit 24 is a copy of the computation chart used during the inspection. Tr. 207.²⁰
35. DEA investigators found that the HMC had a shortage of 40 mg of methadone diskettes²¹ (a .01% difference) and an overage of 2,954 mg of liquid methadone (a 1.9% difference). GE-24; *see* Tr. 207-09.²²
36. The methadone diskettes variance did not raise concerns that the HMC was diverting methadone tablets. Tr. 225. However, the liquid methadone variance could not be accounted for by overfilling, and was not a small or expected variance. Tr. 220-21, 230.

¹⁸ There was a gap in the monthly perpetual records due to Mrs. Ozumba's absence for a family vacation. Tr. 878-80; *see* GE-27. Nonetheless, at that time, the HMC's nurses still conducted opening inventories, maintained daily dispensing records, and conducted closing inventories each day. Tr. 878.

¹⁹ If a registrant counts its controlled substances every day and records that count in a manner that satisfies the Code of Federal Regulations' biennial inventory requirements, that daily inventory is considered to be an adequate biennial inventory. Tr. 246.

²⁰ The purchases reflected on GE-25 are recorded under the "purchases/receipts" column of GE-24. Tr. 207-08.

²¹ This equals just one methadone tablet. Tr. 251.

²² *But see* Tr. 629 (Bultron testifying that, during the 2006 inspection, a DEA investigator told her that the HMC's inventory balanced out, but Bultron could not recall whether the investigator was a man or a woman).

37. Following the inspection, the DEA conducted a closing interview with Mrs. Ozumba and gave her an opportunity to explain both variances. Tr. 250, 881. Initially, the variance for methadone diskettes was greater than just 40 mg. Tr. 251. Mrs. Ozumba produced an explanation, which the DEA accepted and applied to reduce the variance to only 40 mg. Tr. 251. However, Mrs. Ozumba did not provide any explanation for the overage of liquid methadone. Tr. 251.
38. On September 26, 2006, the DEA sent Mrs. Ozumba a letter of admonition regarding the 2006 inspection. Tr. 212-14; GE-26. The letter of admonition alleged that the HMC's "[d]ispensing records were not maintained in a complete and accurate manner"²³ as required by federal regulations. GE-26; Tr. 233.
39. In response to the letter of admonition, Mrs. Ozumba sent a letter to the DEA. GE-27; Tr. 238-39. Mrs. Ozumba's letter acknowledged a "gap in monthly perpetual summary records" due to her brief absence from the HMC. GE-27. Mrs. Ozumba indicated that she had conducted training, some of which surpassed federal requirements, such as perpetual inventories.²⁴ GE-27; Tr. 239-40. Bultron, however, did not recall the HMC implementing any new policies, procedures, or trainings after the 2006 inspection. Tr. 638.
40. Mrs. Ozumba's acceptance of responsibility for the variance discovered in 2006 is unclear. Mrs. Ozumba acknowledged the 2006 variance, but believed that it had been resolved. Tr. 930-31. Mrs. Ozumba believed that the issues identified during the 2006 inspection were resolved by her letter, wherein she explained that the "gap in monthly perpetual summary records was accounted or caused by the Director's brief absence due to a family vacation." GE-27; Tr. 690-92; *see* Tr. 694 (asserting that all issues after the 1997 inspection had been resolved). Mrs. Ozumba believed that she provided to DEA a satisfactory explanation resolving the variance within 30 days of the DEA inspection. Tr. 699-702.
41. During the 2006 inspection, the HMC provided the DEA with all the forms or documents it requested, and the HMC was not cited for any errors related to its 222 Forms or biennial inventory. Tr. 630, 881-82.

²³ *Contra* Tr. 881-82.

²⁴ At the hearing, Mrs. Ozumba testified that she created a new form, RE-X, to control the Respondent's inventory of controlled substances in response to the 2006 inspection. Tr. 931-35. However, in GE-27, Mrs. Ozumba mentioned no such form. Moreover, Garnett credibly testified that he created RE-X in 2012. Tr. 977. Therefore, I do not find Mrs. Ozumba's testimony on this point to be credible.

VI. The 2011 Inspection²⁵

A. Recordkeeping Procedures Before the 2011 Inspection

42. Throughout Franks' employment at the HMC, including prior to the 2011 inspection, Franks counted the medicine and balanced the HMC's controlled substance inventory at the end of each day. Tr. 152. There were occasions when the morning inventory count did not match the previous day's closing inventory count. Tr. 153. When this happened, Franks would alert Mrs. Ozumba. Tr. 153. Likewise, at the end of each day, Franks verified that her records matched the physical count of remaining medication at the HMC. Tr. 163-64. Franks recorded the amount of medication she dispensed each day in a file maintained on a computer, printed out the information, and put the printout in a binder. Tr. 164-66. These records were stored in the medication room. Tr. 171. Franks followed these recordkeeping procedures throughout the entire time she worked at the HMC. Tr. 171. Mrs. Ozumba emphasized the importance of keeping accurate records. Tr. 173.
43. While working for the HMC, there were times when Franks ordered controlled substances for the Respondent's clinic. Tr. 154. On those occasions, Franks would sign her name on 222 Forms at Mrs. Ozumba's direction. Tr. 153-54. Respondent's Exhibit BB contains copies of 222 Forms that Franks signed between October 2011 and May 2012. RE-BB, at 1-6, 8; Tr. 155-57.
44. On October 1, 2011, and on numerous days until December 31, 2011, Franks prepared methadone daily dispensing records for the HMC. Tr. 163-70; *see* RE-G-H.²⁶

²⁵ I do not credit Dr. Ozumba's testimony about the 2011 inspection as fully reliable, Tr. 1009-26, because it contains several contradictions and inconsistencies. *E.g.*, *compare* Tr. 1009-10 (stating that Mrs. Ozumba was not present for the inspection), *with* Tr. 1012, 1014-15 (stating that Mrs. Ozumba was present for the inspection); *compare* Tr. 1012 (stating that the HMC produced records to the DEA investigators before following the investigators to the parking lot), *with* Tr. 1014 (stating that the HMC produced records to the DEA investigators after following the investigators to the parking lot). Insofar as Dr. Ozumba's testimony about the 2011 inspection aligns with other witnesses' testimony about the 2014 inspection, I have considered it under the 2014 inspection findings, *infra*. Insofar as Dr. Ozumba's testimony contradicts other witnesses' testimony about either the 2011 or 2014 inspections, I do not merit his testimony as credible in this Recommended Decision.

²⁶ Respondent's Exhibit G contains methadone diskette dispensing records from October 1, 2011, through December 30, 2011. Respondent's Exhibit H contains liquid methadone dispensing records from October 14, 2011, through December 31, 2011. They were offered in evidence to show the type of records the HMC was maintaining around the time of the 2011 inspection. Tr. 854-56.

B. The Inspection

45. In October 2011, the DEA conducted a scheduled inspection of the HMC, with an audit period of one year. Tr. 291-92.
46. Before beginning the inspection, the Case Agent checked the Registrant's Information Consolidated System ("RICS") to see who had signed the Respondent's DEA application. Tr. 277-78. RICS documented that, at one point, Dr. Ozumba signed the application and, at other times, Mrs. Ozumba had signed it. Tr. 279.
47. Mrs. Ozumba signed a Notice of Inspection at 9:57 a.m. on October 11, 2011. GE-3; Tr. 272-73, 276. When the DEA investigators arrived to inspect the HMC, Mrs. Ozumba asked them to come back, stating she did not have the keys to the dosing room. Tr. 280.²⁷ Mrs. Ozumba indicated that she could not get the keys to the dosing room that day. Tr. 280. The investigators insisted on starting the inspection and conducted the interview portion of the inspection that day. Tr. 281, 290. The investigators also confirmed the HMC's dosing hours and informed Mrs. Ozumba that they would return in a day or two. Tr. 282.
48. On October 13, 2011, the investigators returned to the HMC during a time when Mrs. Ozumba had indicated the clinic would be open. Tr. 282. Upon arrival, the investigators found the Respondent's doors locked. Tr. 282. The investigators, however, talked with Franks, who was outside of the HMC. Tr. 149, 282-83, 731. Franks told the investigators that she had finished dispensing for the day and had to go take a test. Tr. 149, 282-83. The DEA investigators were professional and told Franks that they had an appointment with Mrs. Ozumba. Tr. 149-50, 158, 162. Franks advised the investigators that Mrs. Ozumba was not in the building, but Franks contacted Mrs. Ozumba by phone and let the DEA agents speak with her. Tr. 150, 283, 731. During that phone call, Mrs. Ozumba stated that she was unable to come to the clinic and could not get someone else to come to the clinic to complete the inspection that day.²⁸ Tr. 283-84, 731. The DEA investigators returned to their office without conducting the inspection. Tr. 284. Shortly thereafter, Mrs. Ozumba called the DEA office and made arrangements to meet at the HMC later in the afternoon on that same day. Tr. 151, 284.

²⁷ Mrs. Ozumba testified, however, that she could have done the inspection but did not want to because the nurse had already left and because she had a doctor's appointment. Tr. 729

²⁸ In 2011, Mrs. Ozumba suffered from arthritis and chronic pain, as well as some mobility issues. Tr. 882, 1009.

49. On the afternoon of October 13, 2011, DEA investigators, including the Houston Office's diversion program manager ("DPM"), went to the HMC. Tr. 151, 285. When they arrived, Mrs. Ozumba still did not have the keys to the dosing room, but Dr. Ozumba arrived soon thereafter with the keys. Tr. 285. The interaction between the DEA investigators and Mrs. Ozumba became tense and hostile, and the DPM announced that the investigators were leaving. Tr. 285-86, 719-26, 734-35.²⁹ Dr. Ozumba, Mrs. Ozumba, and Clemente Brown, a counselor, pursued the investigators outside of the clinic and persuaded the investigators to return to complete the investigation. Tr. 286-88, 1013; *cf.* Tr. 883.
50. When Franks observed the interactions between the Ozumbas and DEA personnel during the inspection, the interactions were civil and very professional. Tr. 162. However, at times throughout this inspection, the interactions between Mrs. Ozumba and the Case Agent were fairly contentious. Tr. 463, 1015-16.

C. Physical Security

51. The investigators checked the security system at the HMC and determined that it was not working properly. Tr. 288. The security company did not receive signals from various security zones in the clinic. Tr. 289, 533. Additionally, the HMC's dosing room did not have a panic button.³⁰ Tr. 289, 533.

D. 222 Forms

52. The HMC did not produce any methadone 222 Forms from the audit period as requested by the DEA. Tr. 313.³¹ The DEA, however, contacted a methadone supplier, BIRI Roxane, which produced supplier's copies of five methadone 222 Forms on which the HMC had placed orders for methadone. Tr. 306-14; *see* GE-6, at 1-5.

²⁹ The Case Agent testified that the DPM decided to leave because Mrs. Ozumba would not calm down. Tr. 285-86. I do not credit that testimony. I find it more likely that the investigators left because the interactions between the parties remained tense and hostile.

³⁰ Nothing in 21 C.F.R. § 1301.74(l) requires a narcotic treatment program to have a panic button in its dosing room. Tr. 601. However, the DEA can, within its discretion, require that a panic button be installed. Tr. 601; *see* 21 C.F.R. § 1301.74(l). The Case Agent did not know whether, prior to October 2011, anyone had told the HMC that it was required to have a panic button in its dispensing room. Tr. 602.

³¹ *Contra* Tr. 751, 886-87, 890.

E. Biennial Inventory and Dispensing Logs

53. The HMC did not produce a biennial inventory when requested to do so by the DEA. Tr. 477.³²
54. The HMC produced its dispensing logs upon the DEA's request. Tr. 477, 751, 886. Respondent's Exhibit G contains the daily dispensing logs for methadone diskettes from October 1, 2011, to December 30, 2011. Tr. 852-53. Likewise, RE-H contains the daily dispensing logs for liquid methadone from October 14, 2011, to December 31, 2011. Tr. 854-55. Most of these records are from outside of the 2011 inspection's audit period, and these records do not show the actual pharmaceutical name or strength³³ of the drugs represented therein. Tr. 854, 920-24.

F. Conclusion and Aftermath of the Inspection

55. The DEA investigators conducted a closing inventory of methadone at the HMC. GE-4, at 1-2; Tr. 300-02, 748-49. The DEA did not perform a full audit of the HMC's controlled substance inventory because the HMC did not produce the records that the DEA needed in order to conduct an audit. Tr. 477.³⁴
56. Although Mrs. Ozumba produced records during the inspection, many of the records she produced were from outside of the audit period. Tr. 289-90.
57. After two hours, the investigators terminated the inspection. Tr. 290.³⁵ The investigators conducted a closing interview with Dr. and Mrs. Ozumba and told them: (1) which

³² *Contra* Tr. 751, 890. Mrs. Ozumba testified that the HMC maintained a biennial inventory. Tr. 888.

³³ The HMC, however, only ordered one strength of methadone diskettes (40 mg) and one strength of liquid methadone (1 mg/mL). Tr. 924-25.

³⁴ *Contra* Tr. 722-23, 887, 890, 1012 (Both Dr. and Mrs. Ozumba testified that they produced the records requested by the DEA investigators, but that the investigators refused to look at them).

³⁵ *Compare* Tr. 734 (stating that the DEA investigators left because Mrs. Ozumba refused to surrender her DEA registration), *with* Tr. 1026 (noting that Dr. Ozumba did not hear the investigators ask Mrs. Ozumba to surrender the Respondent's registration). Additionally, Mrs. Ozumba testified that the investigators took the HMC's documents with them when they left the clinic. Tr. 736-38, 754. I do not find this testimony to be credible, particularly because Mrs. Ozumba later testified that she was unsure whether the DEA took any documents from the clinic. Tr. 755.

documents they had not provided to the investigators; and (2) what physical security issues the DEA had discovered.³⁶ Tr. 290-91.

58. After the inspection, the DEA noted that the HMC committed the following violations: failure to maintain a biennial inventory; failure to maintain complete and accurate records; failure to preserve 222 Forms; failure to produce adequate power of attorney documents; and failure to maintain adequate physical security of its controlled substance inventory. Tr. 318-19.
59. The DEA gave the HMC a short time period to correct its physical security issues. Tr. 290. Within a week, the HMC corrected those issues. Tr. 291, 533, 739-40, 901.
60. Based upon the results of the inspection, DEA pursued a civil fine from the Respondent. Tr. 291. The United States Attorney's Office handled the case against the Respondent, which dealt solely with alleged recordkeeping violations. Tr. 1055.
61. The HMC eventually negotiated a settlement with the United States Attorney's Office. Tr. 1056-57. Mrs. Ozumba signed a "Stipulated Agreement" on March 26, 2013, to settle the violations found in 2011, but she is not sure³⁷ if she reviewed it before she signed it. GE-7; Tr. 708-10. Although Mrs. Ozumba believed that she had done nothing wrong, she signed the Stipulated Agreement because she did not have "a lot of options." Tr. 745.
62. Paragraph 16 of the Stipulated Agreement states that it "does not release Houston Maintenance Clinic from DEA administrative liability under statute, contract or regulation." GE-7, at 6.
63. Paragraph 23 of the Stipulated Agreement states, "The Parties agree that this Agreement does not constitute evidence or an admission by any person or entity, and shall not be construed as an admission by any person or entity, with respect to any issue of law or fact." GE-7, at 7.
64. Mrs. Ozumba specifically declined to accept responsibility for any recordkeeping issues discovered in the 2011 inspection. Tr. 933. Mrs. Ozumba believed that any issues concerning the 2011 inspection had been resolved. Tr. 694.

³⁶ I do not credit Mrs. Ozumba's testimony that DEA did not conduct a closing interview concerning the 2011 inspection because the security system at the HMC was brought up to standards about a week after the inspection. Tr. 290-91; *see also* Tr. 901.

³⁷ Mrs. Ozumba testified that no one discussed the agreement with her before she signed it. Tr. 710. When challenged on that statement, however, she admitted that her attorney explained the contents of the agreement to her. Tr. 710-11.

G. Recordkeeping Changes After the 2011 Inspection

65. In May 2012, the HMC kept daily dispensing logs, but did not use the daily inventory form, which Garnett had created for the HMC, RE-X. Tr. 963, 1004. Instead, clinic nurses recorded the daily inventory on the daily dispensing logs. RE-A; Tr. 963, 1000-01. The HMC maintained its perpetual inventory in a Microsoft Word document and in paper files. Tr. 954, 956.
66. In 2012, Garnett designed an Excel spreadsheet for the HMC for use as a perpetual inventory. Tr. 952-59. The Excel spreadsheet contained functions for automatic addition and subtraction. Tr. 956. The first entry under the beginning balance for controlled substances on the spreadsheet was taken from the closing inventory at the last DEA inspection. Tr. 957. In 2012, Garnett created the spreadsheet format for pages one and two of RE-C. Tr. 960, 982. These pages do not indicate an ending balance for any particular day except the last day of the month. Tr. 989, 1001-02. Further, these pages do not document any physical inventory of the HMC's controlled substances. Tr. 989.
67. Prior to October 2013, Garnett formatted the HMC's daily dosing sheet. Tr. 977; RE-A. Garnett automated the HMC's daily dosing sheet; after entries are typed into the sheet, data is automatically generated. Tr. 977, 1004. Anything handwritten on the daily dosing sheet is entered into the electronic dosing sheet by a nurse. Tr. 978.

VII. The 2014 Inspection

68. Prior to the 2014 inspection, McSwain and other nurses employed by the HMC helped prepare daily dispensing records at the clinic. RE-A, at 85-318; RE-B, at 91-338; Tr. 103-04. These dispensing records were kept in an Excel spreadsheet. Tr. 99-100.³⁸
69. McSwain and other employees generated a perpetual inventory on a monthly basis for the HMC, using the daily dosing records. Tr. 114. The perpetual inventory was generated by totaling all of that month's daily records. Tr. 114. When the HMC received orders of controlled substances, McSwain increased the inventory on the Excel spreadsheet

³⁸ For example, on page 91 of RE-B, the daily dosing total of 3,500 units of liquid methadone was entered into the Excel spreadsheet. Tr. 126-29, 138.

accordingly. Tr. 115. On any given day, the incoming nurse could look at the perpetual inventory and know the prior day's ending inventory. Tr. 129.³⁹

70. While McSwain worked at the HMC in 2014, its daily dispensing logs always balanced with its monthly records. Tr. 115.

A. Beginning of the Inspection

71. The DEA inspected the HMC on October 14, 2014 with an audit period of October 1, 2013, through October 14, 2014. GE-9, at 1; Tr. 603.
72. On October 14, 2014, DEA investigators came to the HMC before 9:15 a.m., to conduct an inspection. Tr. 87, 324; *see* GE-11. The HMC was still dosing when the DEA arrived. Tr. 87-88, 324.⁴⁰ The investigators met with McSwain, who was the dispensing nurse at that time, and explained that they were there to conduct an inspection. Tr. 324.
73. Mrs. Ozumba was not at the clinic at the time of the inspection because she was recovering from knee surgery and was in a great deal of pain. RE-Z; Tr. 88, 123, 324, 890, 893, 1017, 1035, 1039. When Mrs. Ozumba was contacted by phone, she requested that the DEA investigators come back to conduct the inspection in a couple of weeks. Tr. 324.
74. Throughout the October 2014 inspection, the DEA investigators were professional and were not rude. Tr. 87-89, 100.⁴¹ Likewise, Dr. Ozumba and the Respondent's employees were professional and cooperative throughout the inspection. Tr. 1046.
75. After dosing was concluded, but before Dr. Ozumba arrived at the HMC, the DEA investigators inventoried the controlled substances at the clinic at 9:15 a.m.⁴² GE-11; Tr. 88, 343-45, 1017-18, 1020.

³⁹ Garnett testified, however, that using RE-C, at 1, you could not tell what the inventory was on any certain day, except for the last day of the month. Tr. 989, 1001-02.

⁴⁰ The DI testified that the DEA investigators arrived after dispensing was completed. Tr. 1047. In light of conflicting testimony and GE-11, showing that the closing inventory was taken at 9:15 a.m., I do not credit the DI's testimony on this issue.

⁴¹ *Contra* Tr. 1022 (Dr. Ozumba testified that the DEA investigator was oppressive, verbally combative, and degrading, but he could not detail the investigator's statements). I do not credit Dr. Ozumba's testimony on this issue.

⁴² *Contra* Tr. 1040, 1044 (stating that the investigators did not conduct any part of the investigation, including the inventory, before Dr. Ozumba arrived).

76. Dr. Ozumba came to the HMC between noon and 1:00 p.m. Tr. 88, 324-25, 765-66, 1009, 1017, 1019, 1040. Upon his arrival, Dr. Ozumba signed a Notice of Inspection. GE-8; Tr. 321-25, 1018-19.
77. The DEA gave Dr. Ozumba a list of the documents that the DEA needed to review. Tr. 325. Dr. Ozumba had access to Mrs. Ozumba's office, and had keys to all of the doors in the HMC and Mrs. Ozumba's office. Tr. 90, 732-33. Dr. Ozumba was familiar with where the HMC's records were stored, but he did not know where all of the records were kept, including the 222 Forms. Tr. 1023.
78. McSwain, Dr. Ozumba,⁴³ and the DEA investigators all spoke to Mrs. Ozumba on the phone. Tr. 89, 91, 100, 325, 373, 431, 536, 716-17, 766-67, 784, 1039, 1041, 1052.⁴⁴ McSwain did not hear any of the conversations between the DEA investigators and the Ozumbas. Tr. 110-11, 124, 140-41. Mrs. Ozumba made suggestions about where to look for the documents that the DEA had requested. Tr. 91, 124-25, 716-17, 767-68, 784, 1041.⁴⁵ However, Mrs. Ozumba testified that all of the required documentation, including daily dispensing logs, inventories, and 222 Forms, was at the HMC at that time. Tr. 894-95.
79. Dr. Ozumba testified that he does not believe that the 2014 inspection would have gone better if Mrs. Ozumba had been present for the inspection. Tr. 1024. He also testified, however, that Mrs. Ozumba knew where the 222 Forms⁴⁶ and buprenorphine logs were located. Tr. 1025; *see also* Tr. 91 (McSwain testifying that when Mrs. Ozumba was on the phone, she was only suggesting places to look for documents.)

⁴³ *Contra* Tr. 1032 (stating that Dr. Ozumba did not talk to his wife during the inspection).

⁴⁴ It is unclear whether Mrs. Ozumba was under the influence of post-surgery medication at this time. *Compare* Tr. 124 (stating that Mrs. Ozumba did not seem to be under the influence of medication and seemed to be her normal, spirited self), *with* Tr. 928-29 (stating that Mrs. Ozumba was taking tramadol, hydrocodone, prednisone, protonix, a muscle relaxer, and anxiety medication at that time), *and* Tr. 716, 772 (stating that she was not cognizant and was only pretending to be normal). Mrs. Ozumba was cognizant enough, however, to ask for the inspection to be conducted at a later date. Tr. 324.

⁴⁵ McSwain testified that Mrs. Ozumba did not suggest they look on the computer for documents. Tr. 133. Mrs. Ozumba's testimony on this point was contradictory; she first said that she did not tell McSwain to look on her computer, but then said that she told McSwain to look on her computer. Tr. 769-72. Further, the Case Agent found McSwain creating a document on the computer at Mrs. Ozumba's direction. Tr. 92-94, 326.

⁴⁶ Tr. 898-99, 901-02. Mrs. Ozumba testified that the 222 Forms provided at the hearing in RE-BB were maintained in the clinic in a locked cabinet. Tr. 898.

B. Biennial Inventory

80. The Case Agent requested the biennial inventory for the HMC's controlled substances. Tr. 92, 1043. A biennial inventory reflects a physical count of controlled substances on hand on a specific day. Tr. 371. The HMC did not provide a biennial inventory. Tr. 329, 521.⁴⁷ During the inspection, however, Mrs. Ozumba was talking with McSwain by phone, instructing her how to create a biennial inventory. Tr. 92-93. The HMC provided the DEA with annual inventories for its methadone diskettes and liquid methadone, as well as its 2 mg and 8 mg buprenorphine. GE-10, at 1-4; Tr. 368-70, 584.

C. Buprenorphine Inventory

81. The Case Agent looked for the HMC's buprenorphine (suboxone) inventory. Tr. 94, 325-26. McSwain was not aware of that inventory; though, she did know that the daily dosing records of the patients who received buprenorphine were kept in a manila envelope. Tr. 93-95, 132. The HMC only had about three patients who received buprenorphine. Tr. 94, 117. After requesting the buprenorphine inventory, the Case Agent entered the dosing room and found McSwain working on a computer, creating a buprenorphine inventory at Mrs. Ozumba's direction. Tr. 92-94, 326. The Case Agent told McSwain to stop what she was doing and print off what she had without further modifications. Tr. 326. During the inspection, the HMC did not produce an initial inventory for buprenorphine. Tr. 456.

D. 222 Forms

82. The DEA requested 222 Forms from the HMC. Tr. 89, 132-33, 1043. The HMC provided some 222 Forms to the DEA. GE-13, at 1-4; Tr. 353-54. However, one 222 Form, dated September 9, 2014, was incomplete because it does not show the number of packages received or the date of receipt. GE-13, at 1; Tr. 354-55. Another 222 Form was signed by Dr. Ozumba, not Mrs. Ozumba. GE-13, at 2; Tr. 355. The Respondent provided additional

⁴⁷ Mrs. Ozumba testified that there was a biennial inventory on a "backup" drive, but McSwain did not know about it. Tr. 770.

222 Forms to DEA after the date of the inspection, but the DEA did not include the information contained on those forms in its audit of the HMC because they were received after the audit had been completed. Tr. 354, 366-67.

83. The HMC provided the DEA with a list of controlled substances that it purchased between January 15, 2014 and September 12, 2014. GE-12; Tr. 347-49. The DEA obtained a similar list from BIRI-Roxane, the Respondent's supplier. GE-15; Tr. 351, 359-63.
84. The documents in RE-E are requisition forms for controlled substances, which are not forms that the DEA required the HMC to maintain. Tr. 459-61. In addition, they were not produced until this case was being prepared for the DEA administrative hearing. Tr. 460, 538.⁴⁸

E. Dispensing Records

85. The DEA requested the HMC's dosing records. Tr. 135, 1043. The HMC provided the DEA with dispensing logs for methadone diskettes and liquid methadone. Tr. 105, 107, 422, 456-57, 607, 1043-44; *see* RE-A-B. Respondent's Exhibit A contains the daily dosing logs for methadone diskettes from October 1, 2013, through October 14, 2014. RE-A; *see* Tr. 847-48, 915. Respondent's Exhibit B contains the daily dosing logs for liquid methadone from September 30, 2013, to October 31, 2014. RE-B; Tr. 849-50.
86. During the October 2014 inspection, no dispensing logs were provided for buprenorphine, and McSwain told the Case Agent that the HMC did not have dispensing logs for buprenorphine. Tr. 378, 422, 455. While RE-AA contains dispensing logs for buprenorphine, those logs were not provided during the inspection and were not produced by the Respondent until preparing for the DEA administrative hearing. Tr. 461-62, 538.

⁴⁸ While it is possible to compare RE-E with GE-15 to calculate the quantity of controlled substances the Respondent received from BIRI-Roxane, it was the Respondent's responsibility to maintain its copy of 222 Forms, and to have them readily retrievable at the time of the inspection. Tr. 424, 460; *see also* 21 C.F.R. §§ 1304.04(f)(2), 1305.17(a).

F. Variances

87. The investigators conducted a closing inventory as a part of their inspection. GE-11. The investigators used a computation chart to conduct their audit of the HMC's inventory. GE-9, at 1-9; Tr. 375-80. The closing inventory indicated that the HMC had an overage of 1,200,000 dosage units of methadone diskettes and an overage of 500,251 dosage units of liquid methadone. GE-9. The closing inventory also indicated that the HMC had a shortage of 30 buprenorphine 2 mg tablets and 175 buprenorphine 8 mg tablets. GE-9. These overages and shortages were calculated using only the HMC's receipt records; they did not incorporate BIRI-Roxane's (or other supplier's) records, because the audit focused on only the Respondent's records. Tr. 379, 421-24, 496-98.

G. Power of Attorney Forms

88. The DEA requested the HMC's power of attorney forms. Tr. 96, 1043. McSwain knew that a power of attorney form had been prepared, but she could not find it. Tr. 96.
89. Dr. Ozumba provided the Case Agent with two power of attorney forms. Tr. 327-29, 389-92. The first form was a blank form that was prepared for Austin Orette's ("Dr. Orette") signature. GE-21; Tr. 390. Dr. Orette was not authorized to sign a power of attorney on behalf of the HMC because Dr. Orette was not the HMC's DEA registrant. Tr. 598-99. The Case Agent explained to Dr. Ozumba that Dr. Orette did not have the authority to execute a power of attorney on behalf of the HMC. Tr. 327, 390-93.
90. On the day of the inspection, McSwain signed a new power of attorney form, which was given to the DEA. Tr. 97. Dr. Ozumba gave the Case Agent a power of attorney form, purportedly signed (without any witnesses) on February 8, 2014, with "C. Ozumba" written in as the grantor, no name written in as the "attorney-in-fact," and McSwain's name signed as the "person granting power." GE-20; Tr. 328-29, 395-96.

H. Conclusion and Immediate Aftermath of the Inspection

91. The HMC was unable to provide the DEA with all of the documents the DEA had requested on the date of the inspection. Tr. 91, 94, 105, 107, 132, 135-36, 329, 437-39, 455, 461-62, 521, 538, 1023.
92. At the end of the inspection, the investigators took some documents they had requested with them and they left a receipt, which listed everything that the investigators took and the additional documents that the DEA needed. Tr. 96, 1022, 1028-29, 1033. The documents the DEA took included some of the 2014 dispensing logs. Tr. 107-10.
93. A few days after the inspection, but after the DEA's audit was completed, Mrs. Ozumba directed McSwain to retrieve a binder from Mrs. Ozumba's office and fax the documents contained therein to the DEA. Tr. 98, 333. McSwain faxed the records that are contained in GE-14 to the DEA on October 17, 2014. Tr. 333. Some of those documents were the documents that the DEA investigators requested during the inspection, such as a power of attorney form and 222 Forms. Tr. 98-99. However, most of the faxed documents were from outside of the audit period. Tr. 333; *see* GE-14. Only seven of the faxed pages were relevant to the DEA's audit. Tr. 340-42; *see* GE-14, at 3-9.
94. The power of attorney that was faxed to the DEA on October 17, 2014, was a form prepared for Dr. Orette's signature; it was signed, however, by Mrs. Ozumba, who was the person who had authority to sign a power of attorney on behalf of the HMC at that time.⁴⁹ GE-14, at 2; Tr. 335, 337-39; *see* Tr. 98-99.
95. Because of Mrs. Ozumba's poor physical condition, the Case Agent attempted to conduct a telephonic closing interview with Mrs. Ozumba. Tr. 330-32. Mrs. Ozumba, however, did not cooperate in the telephonic closing discussion, so the interview was terminated early. Tr. 332.

⁴⁹ Later, the Respondent submitted this same power of attorney form, but it was signed by Dr. Orette. RE-F. A comparison of page two of GE-14 and page one of RE-F reveals that the latter document is an alteration of the former. All of the handwritten entries on both documents are identical. On close examination, it is possible to see remnants of Mrs. Ozumba's signature to the left of and below Dr. Orette's signature. No explanation was provided by the Respondent concerning why the document was altered. The Respondent did not produce RE-F until it was preparing for the hearing in this case. Tr. 538. Nonetheless, RE-F represents that Dr. Orette was "authorized to sign the current application for registration" on the Respondent's behalf. RE-F, at 2; *see* Tr. 102, 137. Dr. Orette, however, has never had the authority to sign the Respondent's DEA registration application. *See* Tr. 659.

96. After the attempted closing interview, the DEA notified Mrs. Ozumba that an informal hearing would be conducted on December 10, 2014. GE-17; Tr. 380-82. Mrs. Ozumba was notified that the hearing concerned the HMC's failure to: maintain complete and accurate records of each controlled substance received, sold, and delivered; conduct a biennial inventory; conduct an initial inventory of buprenorphine; preserve 222 Forms; indicate the date of receipt of 222 Forms; execute a power of attorney authorizing an alternate person to sign 222 Forms; and completely and accurately complete daily dispensing logs. GE-17, at 1-2. In response, Mrs. Ozumba, on behalf of the HMC, sent a letter to the DEA on December 4, 2014. GE-18; Tr. 383-84. Therein, Mrs. Ozumba requested that the hearing be rescheduled to March 11, 2015, to allow her to obtain legal counsel for the HMC, and to accommodate Mrs. Ozumba's continuing post-operative medical issues. GE-18; Tr. 385. The DEA denied the request. GE-19; Tr. 388-89.
97. Mrs. Ozumba does not believe that the HMC committed any violation in 2014. Tr. 934. Mrs. Ozumba believes that any issue found by the DEA has been resolved. Tr. 694. Following this inspection, Mrs. Ozumba moved all of the HMC's 222 Forms to the clinic's dispensing room. Tr. 934. Mrs. Ozumba accepted responsibility for her absence during the inspection, but believed that, if the DEA were to conduct an inspection now, all of the needed records would be readily available. Tr. 934.

I. Records Produced For the DEA Administrative Hearing

98. During the pendency of this case, the HMC provided the DEA with 222 Forms from the 2014 audit period for the first time.⁵⁰ RE-BB, at 21-29; Tr. 437-39. One of these 222 Forms was an altered copy of a document previously given to the DEA during the 2014 inspection. Tr. 439; *compare* GE-13, at 1, *with* RE-BB, at 29 (reflecting alterations on the numbers of packages received and the date on which they were received).
99. During the pendency of this case, the HMC also provided requisition forms for buprenorphine. RE-E; Tr. 867, 869. However, the HMC was not required to maintain these forms. Tr. 459-61.⁵¹ Moreover, RE-E was not provided to the DEA until this case was

⁵⁰ *Cf.* Tr. 716.

⁵¹ *Contra* Tr. 866 (stating that the Respondent views this documentation as the "equivalent" of 222 Forms).

already pending. Tr. 460, 538. While it is possible to compare RE-E with GE-15 to calculate the quantity of controlled substances the HMC received from BIRI-Roxane, it was the Respondent's responsibility to maintain its copies of 222 Forms and to retrieve them within a reasonable time during the inspection. Tr. 424, 460; *see also* 21 C.F.R. §§ 1304.04(f)(2), 1305.17(a).

100. Government's Exhibit 10, provided to the DEA during the 2014 inspection, *see* Tr. 584, and Respondent's Exhibit E, provided to the DEA during this hearing, both purport to report the HMC's inventory in 2014. *Compare* GE-10, *with* RE-E. A comparison of the two exhibits reveals that many of the recorded figures therein do not match, including the buprenorphine 2 mg, Tr. 559-66; *compare* GE-10, at 3, *with* RE-E, at 5, and the buprenorphine 8 mg, Tr. 566-71, *compare* GE-10, at 4, *with* RE-E, at 8. Notably, the two exhibits reflect different: beginning balances of buprenorphine 2 mg tablets in June 2014; amounts dispensed in June, August, September, and October 2014; and ending balances in June through October 2014.⁵² *Compare* GE-10, at 3-4, *with* RE-E, at 5, 8.
101. Respondent's Exhibit C was compiled using the HMC's daily dosing reports, but it was not presented to the DEA⁵³ until this case was already pending before me. Tr. 540, 794-96, 863, 866. Pages one and two of RE-C are monthly summaries of the HMC's methadone diskette daily dosing perpetual inventory. RE-C, at 1-2; Tr. 116, 857. The beginning balance on this form is taken from the last DEA audit. Tr. 857-58. This information was maintained on Mrs. Ozumba's backup computer drive. Tr. 861-62. Pages three and four of RE-C are similar, except they concern liquid methadone. RE-C, at 3-4; Tr. 117, 863-64.
102. Government's Exhibit 10, provided to the DEA during the 2014 inspection, and Respondent's Exhibit C, provided to the DEA during this hearing, both purport to report the HMC's inventory. *Compare* GE-10, *with* RE-C. A comparison of the two exhibits reveals that many of the reported figures therein do not match, specifically, the methadone 40 mg diskettes, Tr. 541-49, *compare* GE-10, at 1, *with* RE-C, at 1, and the liquid methadone, Tr. 551-59, *compare* GE-10, at 2, *with* RE-C, at 3. For example, the two exhibits record different: amounts of diskettes dispensed in November and December 2013; ending balances in October through December 2013; amounts of liquid methadone dispensed in October

⁵² Page four of GE-10 contains no entries for September and October 2014.

⁵³ During the inspection, the HMC produced different versions of pages one through four of RE-C. Tr. 540.

through December 2013; and ending balances of liquid methadone in October through December 2013. *Compare* GE-10, at 1-2, *with* RE-C, at 1, 3.

103. The HMC did not produce buprenorphine dispensing logs during the inspection. Tr. 455. Respondent's Exhibit AA is the Respondent's monthly buprenorphine dispensing logs for July 2014 through September 2014. Tr. 117-23. These logs were not provided to the DEA during the 2014 inspection, and were only given to the DEA when this case was already pending. Tr. 132, 135-36, 461-62, 538. Mrs. Ozumba testified that the Respondent's nurses were required to keep daily dosing logs for buprenorphine. Tr. 870.
104. Government's Exhibit 10, Respondent's Exhibit E, and Respondent's Exhibit AA all contain the Respondent's records for its buprenorphine 8 mg tablets. Tr. 592-96, 869. A comparison of the three exhibits reveals several inconsistencies. For example, in June 2014, RE-E records that the HMC dispensed 104 mg of buprenorphine 8 mg tablets, whereas RE-AA records that the HMC dispensed 108 mg of buprenorphine 8 mg tablets, and GE-10 records that the HMC dispensed only 56 mg of buprenorphine 8 mg tablets. *Compare* RE-E, at 8, *with* RE-AA, at 1, *and* GE-10, at 4. Likewise, in September 2014, RE-E records that the HMC dispensed 64 mg of buprenorphine 8 mg tablets, whereas RE-AA records that the HMC dispensed 68 mg of buprenorphine 8 mg tablets, and GE-10 has no entry. *Compare* RE-E, at 5, *with* RE-AA, at 5, *and* GE-10, at 4.

VIII. Remedial Measures

105. After the 2014 inspection, Mrs. Ozumba hired an office manager for the HMC, Garnett, who is experienced in hospital management. Tr. 903. Mrs. Ozumba indicated that she would also be willing to hire a "compliance specialist." Tr. 904.
106. In 2015, Garnett returned to work at the HMC. Tr. 964. At that time, the HMC maintained a perpetual inventory in Excel, but the program did not auto-populate. Tr. 964. The HMC now still uses Excel to maintain its perpetual inventory. Tr. 949.

107. The HMC still maintains a daily dispensing log for each patient. Tr. 951. The HMC's nurses also conduct a physical inventory every day and record the results on forms like RE-X. Tr. 950-52, 965. The data from this daily inventory is entered into the perpetual inventory using a software program called "Methware." Tr. 952, 966. The HMC's perpetual inventory keeps track of the beginning balance, amount dispensed, new receipts, any spillage, and ending balance. Tr. 953-54. After each daily entry is entered into the "Methware" program, the information in that entry cannot be changed. Tr. 967.

ANALYSIS

I. Applicable Law

To receive and maintain a DEA COR, a narcotic treatment program must "comply with standards established by the Attorney General respecting (i) security of stocks of narcotic drugs for such treatment, and (ii) the maintenance of records (in accordance with section 827 of this title)" 21 U.S.C. § 823(g)(1)(B) (2012).⁵⁴ A narcotic treatment program's DEA COR "may be suspended or revoked . . . upon a finding that the registrant has failed to comply with any standard referred to in section 823(g)(1) of this title." 21 U.S.C. § 824(a) (emphasis added). Reading these two provisions of the Controlled Substances Act together, a narcotic treatment program's DEA COR may be suspended or revoked because of any failure to maintain: (1) the physical security of controlled substances; or (2) proper records. 21 U.S.C. §§ 823(g)(1)(B), 824(a); *see Turning Tide, Inc.*, 81 Fed. Reg. 47411 (2016).⁵⁵ As *Turning Tide* discussed in detail, the DEA need not analyze the public interest factors when deciding whether revocation of a narcotic treatment program's registration is appropriate. *Turning Tide*, 81 Fed. Reg. at

⁵⁴ Before and during the hearing, I asked both parties to state their positions concerning whether a public interest analysis applied to this case. *See* Tr. 21-24; *see also* Tr. 1077-78; ALJ-25. The Government argued that a public interest analysis does not apply. Tr. 23. The Respondent, however, argued that a public interest analysis should apply, and that the factors to be considered should include: the HMC's service towards a low-income demographic; the HMC's compliance with state laws; and the HMC's general history of compliance with controlled substance laws. Tr. 24. The OSC specifically alleges that the Respondent's COR should be revoked under 21 U.S.C. § 824(a). However, because the Government stated at the beginning of the hearing that it did not believe that a public interest analysis applied in this case, and the OSC also cites 21 U.S.C. § 823(g), the Respondent was on notice that the Government would argue in favor of revocation under 21 U.S.C. § 823.

⁵⁵ The decision in *Turning Tide* was not published in the Federal Register until after the conclusion of the hearing in this case.

47412-13 (examining the statutory construction of 21 U.S.C. § 823(g)(1) in comparison with every other category of registration set forth in Section 823). The DEA “will not hesitate to revoke the registration of a n[a]rcticotic treatment program that fails to meet its statutory and regulatory obligations to provide adequate security and recordkeeping.” *Queens County Med. Soc’y Drug Line*, 50 Fed. Reg. 2098, 2100 (1985).

A narcotic treatment program’s registration may be revoked if the narcotic treatment program fails to keep its records as required by federal regulations. 21 U.S.C. §§ 824(a), 823(g)(1)(B); *see, e.g., Herbert Berger, M.D.*, 52 Fed. Reg. 17645, 17645-46 (1987). In this case, the Government alleged that the HMC committed several recordkeeping violations related to: (1) receipt and dispensation records of controlled substances; (2) 222 Forms; (3) retrievable records; (4) biennial and buprenorphine inventories; and (5) controlled substance variances. Additionally, under 21 U.S.C. § 824(g), narcotic treatment programs are required to “maintain security of stocks of narcotic drugs.” *Queens County*, 50 Fed. Reg. at 2098. In this case, the Government alleged that the Respondent failed to maintain adequate physical security of its controlled substances.

A. Receipt and Dispensation Records

A narcotic treatment program must “maintain, on a current basis, a complete and accurate record of each substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of.” 21 C.F.R. § 1304.21(a); *see* 21 U.S.C. § 827(a)(3). These records must detail, among other things: (1) the types and quantities of controlled substances received and dispensed; (2) the names and addresses of the persons who receive controlled substances; (3) the dates of dispensing; and (4) the names or initials of the persons who dispense or administer controlled substances. 21 C.F.R. § 1304.22(c).

Further, narcotic treatment programs must record the controlled substances “administered in the course of maintenance or detoxification treatment of an individual.” 21 C.F.R. § 1304.03(d). Specifically, narcotic treatment programs must record, in a dispensing log for each controlled substance, the following information:

- (1) Name of substance;
- (2) Strength of substance;
- (3) Dosage form;

- (4) Date dispensed;
- (5) Adequate identification of patient (consumer);
- (6) Amount consumed;
- (7) Amount and dosage form taken home by patient; and
- (8) Dispenser's initials.

Id. § 1304.24(a)-(b).

B. 222 Forms

A registrant must record the quantity of controlled substances purchased, along with the dates of receipt of the substances, on a copy of a 222 Form. 21 C.F.R. § 1305.13(e). In reading the plain language of the regulation, the Agency recently determined that incomplete forms alone could not prove a regulatory violation; instead, it required additional proof that the purchaser actually had an obligation, triggered by the receipt of the ordered substances, to complete the forms, but neglected to do so. *Superior Pharmacy I & Superior Pharmacy II*, 81 Fed. Reg. 31310, 31338 (2016).⁵⁶ In other words, the Government must prove that the registrant actually received the ordered controlled substances, but failed to notate it on the 222 Form. This interpretation was reaffirmed by the Agency in *Hills Pharmacy, L.L.C.*, 81 Fed. Reg. 49816, 49842-43 (2016). Additionally, the registrant must maintain Copy 3 of each executed 222 Form separately from all other records of the registrant and make available for inspection for two years. 21 C.F.R. § 1305.17(a), (c).

Generally, only DEA registrants “may obtain and use DEA Form 222 (order forms) or issue electronic orders for [controlled] substances.” 21 C.F.R. § 1305.04(a). This rule has a narrow exception: a DEA registrant may authorize another person to execute 222 Forms on the registrant’s behalf by properly executing a power of attorney. *Id.* § 1305.05(a). The power of attorney document must be preserved, “available for inspection,” *id.*, and “executed by the person who signed the most recent application for DEA registration,” *id.* § 1305.05(d).

⁵⁶ *Superior Pharmacy* was published in the Federal Register on May 18, 2016, before the conclusion of the hearing in this case.

C. Readily Retrievable Records

A registrant's records must be readily retrievable. *Id.* § 1304.04(f)(1) and (2) (requiring narcotic treatment programs to maintain records for Schedule II substances separately from all other records, and records for Schedules III, IV, and V controlled substances either separately or in "such form that the information required is readily retrievable"); *see id.* § 1304.03(e) (requiring mid-level practitioners to maintain readily retrievable records). Required records and inventories "must be kept by the registrant and be available, for at least 2 years from the date of such inventory or records, for inspection and copying by authorized employees of the Administration." *Id.* § 1304.04(a). The DEA defines "readily retrievable" to mean:

that certain records are kept by automatic data processing systems or other electronic or mechanized recordkeeping systems in such a manner that they can be separated out from all other records in a reasonable time and/or records are kept on which certain items are asterisked, redlined, or in some other manner visually identifiable apart from other items appearing on the records.

Id. § 1300.01(b). The DEA "does not require that records be 'instantaneously produced.'" *Edmund Chein, M.D.*, 72 Fed. Reg. 6580, 6593 (2007). The records must be retrievable in a "reasonable time." *Id.* In *Chein*, the DEA briefly discussed and interpreted the definition of "reasonable time:"

While what constitutes "a reasonable time" necessarily depends on the circumstances, under normal circumstances[,] if a practice is open for business, it should be capable of producing a complete set of records within several hours of the request. In this case, I conclude that on the second visit, the clinic's provision of the records within two to three hours complied with the regulation but barely so. To allow a registrant an even greater period of time to produce the records would create an incentive for those who are engaged in illegal activity to obstruct investigations by stalling for time in the hopes that DEA personnel would eventually give up and leave.

Id. The DEA has also noted that "readily retrievable" means producible "upon demand of those DEA officials charged with conducting inspections." *Jeffrey J. Becker, D.D.S.*, 77 Fed. Reg. 72387, 72406 (2012) (citations omitted); *see* 21 C.F.R. § 1304.04(a) (requiring records to be maintained for two years "for inspection and copying by authorized employees of the [DEA]").

D. Biennial and Buprenorphine Inventories

A registrant must record the quantity of each controlled substance it possesses. 21 C.F.R. § 1304.11(c). A registrant must also inventory “all stocks of controlled substances on hand at least every two years.” *Id.* A registrant must keep all inventory records in an accessible form for at least two years after the date of the inventory “for inspection and copying by authorized employees of the [DEA].” *Id.* § 1304.04(a); *see id.* § 1304.04(f). Each inventory must include “a complete and accurate record of all controlled substances on hand on the date the inventory is taken.” *Id.* § 1304.11(a). This requirement applies to all types of controlled substances that a registrant possesses. *See id.* Notably, inventories of a narcotic treatment program’s Schedule II controlled substances must be “maintained separately from all of the records of the registrant.” *Id.* § 1304.04(f)(1).

E. Variances

Controlled substance inventories must “contain a complete and *accurate* record of all controlled substances on hand on the date the inventory is taken.” *Id.* § 1304.11(a) (emphasis added). Physical inventory counts of controlled substances must be accurate. *See id.* § 1304.11(e)(6). Repeated variances in controlled substance inventories “manifest[] a casual indifference to [a registrant’s] obligation to . . . properly account for its supply of narcotic drugs.” *See Queens County*, 50 Fed. Reg. at 2100. Moreover, the inability to account for a significant number of dosage units creates a grave risk of diversion. *Med. Shoppe-Jonesborough*, 73 Fed. Reg. 364, 367 (2008); *see also Paul H. Volkman, M.D.*, 73 Fed. Reg. 30630, 30644 (2008) (finding that “a registrant’s accurate and diligent adherence to this obligation is absolutely essential to protect against the diversion of controlled substances”), *pet. for review denied*, 567 F.3d 215, 225 (6th Cir. 2009).

F. Physical Security of Controlled Substances

Narcotic treatment programs are required to maintain physical security controls for controlled substances as set forth in 21 C.F.R. § 1301.72. The Respondent kept its Schedule II controlled substances in a safe. A safe used to store Schedule II controlled substances must be

equipped with an alarm system which, upon attempted unauthorized entry, shall transmit a signal directly to a central protection company or a local or State police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant, or such other protection as the Administrator may approve.

21 C.F.R. § 1301.72(a)(1)(iii). Section 1301.72 does not require a narcotic treatment program to install a panic button in its dispensing room. *See also id.* § 1301.74(l) (same).

II. The Respondent's Alleged Violations

A. The 1997 Inspection

The Government alleged that, at the time of the 1997 inspection, the HMC had committed four violations: (1) failing to record the amount of controlled substances received; (2) failing to keep 222 Forms; (3) failing to properly maintain daily dispensing records; and (4) having variances in its controlled substances supply. ALJ-1, at 1-2. I find that the Government demonstrated that the HMC committed only the fourth violation.

A majority of the Government's evidence regarding the 1997 inspection related to the fourth allegation. The Government entered evidence showing that the HMC had a shortage of 16,144 mg of methadone tablets and a shortage of 411 mg/mL of liquid methadone. GE-34-36. Mrs. Ozumba admitted that there was a variance in her controlled substance inventory at the time of the 1997 inspection. Tr. 685, 687, 693, 929; *see* GE-37; Tr. 407-09, 675-78. Based upon the Government's undisputed evidence, I find that the HMC had a shortage of methadone tablets and liquid methadone at the time of the 1997 inspection. Therefore, the Government's allegation to that effect is **SUSTAINED** by a preponderance of the evidence, and weighs in favor of revoking the Respondent's COR.

However, the Government did not offer any evidence demonstrating that the HMC committed the first three alleged violations. The Government argued that GE-33-37 showed that

the HMC committed the first three alleged violations. *See* ALJ-27, at 3. However, these exhibits only offer evidence supporting findings that: (1) the HMC had a variance; and (2) that variance was due to some unidentified deficiency in the HMC's records. *See* GE-34-37. The Government did not enter any evidence about the HMC's receipt records or 222 Forms from the 1997 inspection. Therefore, the Government's allegations that the HMC failed to record the amount of controlled substances received and failed to keep 222 Forms are **NOT SUSTAINED**.

Likewise, the Government did not discuss any inadequacies in the HMC's dispensing record. The Government did not enter any evidence specifically showing that the HMC's daily dispensing records were inadequate at the time of the 1997 inspection. There are numerous possible explanations for how the HMC could have had a shortage of liquid methadone and methadone diskettes. One possible explanation is that the HMC failed to accurately record its dispensing in its daily dispensing log. However, that is only a possible explanation, supported by inference rather than substantial evidence. The Government did not allege that, generally, the HMC's receipt and dispensing logs were inaccurate; rather, it alleged that, specifically, the HMC failed to properly maintain daily dispensing logs. Therefore, the Government's allegation that the Respondent failed to properly maintain daily dispensing records in 1997 is **NOT SUSTAINED**.

B. The 1999 Inspection

The Government alleged that, at the time of the 1999 inspection, the HMC committed two violations: (1) failing to maintain complete and accurate records of Schedule II controlled substances received and dispensed; and (2) having variances in its controlled substances supply. ALJ-1, at 2. I find that the Government showed, by a preponderance of the evidence, that the HMC committed both violations.

The Government entered a closing inventory and a computation chart from the 1999 inspection, which showed that the HMC had an overage of 100,810 mg of methadone diskettes and a shortage of 2,591 mg of liquid methadone. *See* GE-29-30; Tr. 37, 40; *see also* GE-31; Tr. 398-401, 411-13. These documents were corroborated by the Unit Chief's credible testimony that she personally recalled an overage of one of the Respondent's controlled substances and a deficit of the other. Tr. 30-31. While Mrs. Ozumba signed an MOU on behalf of the HMC in

March of 2000, which cited the HMC for its failure to maintain a complete and accurate record of Schedule II controlled substances received and distributed, the MOU did not clearly admit or deny that there was a variance at the time of the 1999 inspection. *See* Tr. 685, 689, 696-98; *see also* GE-32. At the hearing, Mrs. Ozumba accepted responsibility for the variance found in 1999, and then denied responsibility for it. *See* Tr. 685, 689. She subsequently went on to specifically deny having a variance of 100,810 mg of diskettes in 1999, stating that she has never had a variance that large. Tr. 696-97; *see* GE-30. I find that the closing inventory, computation chart, and the Unit Chief's testimony, when considered cumulatively, show that the HMC had significant variances in its controlled substances supply at the time of the 1999 inspection. Therefore, the Government's allegation to that effect is **SUSTAINED**. By logical inference, because the HMC had a variance in its controlled substance supply, the HMC's records were not accurate.⁵⁷ Therefore, the Government's allegation that the HMC failed to keep complete and accurate records of the Schedule II controlled substances it received and dispensed is **SUSTAINED**, and weighs in favor of revoking the Respondent's COR.

C. The 2006 Inspection

The Government alleged that, at the time of the 2006 inspection, the HMC committed two violations: (1) failing to keep and maintain daily dispensing logs of controlled substances; and (2) having variances in its controlled substances supply. ALJ-1, at 2. I find that the Government showed, by a preponderance of the evidence, that the HMC committed only the second violation.

The Government entered a closing inventory and computation chart from the 2006 inspection showing that the HMC had a shortage of 40 mg⁵⁸ of methadone tablets and an overage of 2,954 mg of liquid methadone. GE-23-24; Tr. 224. The methadone diskettes variance did not raise concerns that the HMC was diverting methadone tablets; however, the liquid methadone variance could not be accounted for by overfilling and was not a small or expected variance. Tr. 220-21, 225, 230. Moreover, while Mrs. Ozumba provided DEA with an explanation regarding the variance for the methadone diskettes, which resulted in a reduction of the variance

⁵⁷ Unlike the Government's specific recordkeeping allegation concerning the 1997 inspection, the 1999 allegation concerning recordkeeping errors is a general allegation.

⁵⁸ *See* Tr. 251 (indicating that this amount is the equivalent of one methadone tablet).

to 40 mg, she did not provide any explanation for the overage of liquid methadone. Tr. 251. Furthermore, the Group Supervisor testified that she personally observed the count of the HMC's controlled substances, that the count was recorded in the computation chart, and that the computation chart was accurate. Tr. 205-11. The Group Supervisor also specifically mentioned in her testimony that there was a variance, and Mrs. Ozumba specifically acknowledged that there was a variance. Tr. 220, 250-51, 930; *see* Tr. 699-702. It is important to note that Mrs. Ozumba's acceptance of responsibility for the variance discovered at the time of the 2006 inspection was unclear. She acknowledged the variance, but believed that it had been resolved by her letter explaining the gap in the monthly perpetual summary records. Tr. 930. I find that the closing inventory, computation chart, Group Supervisor's testimony, and Mrs. Ozumba's ambiguous acceptance of responsibility, when considered cumulatively, show that the HMC had variances in its controlled substances supply at the time of the 2006 inspection. Therefore, the Government's allegation to that effect is **SUSTAINED**, and weighs in favor of revoking the Respondent's COR.

However, the Government did not enter any evidence specifically showing that the HMC's daily dispensing records were inadequate at the time of the 2006 inspection. In fact, the record evidence establishes that the HMC produced all of the forms or documents requested by the DEA in 2006. Tr. 630. There are numerous possible explanations for how the HMC could have had a shortage of one methadone diskette and an overage of liquid methadone. One possible explanation is that the HMC failed to accurately record its dispensing in its daily dispensing log. However, that is only a possible explanation, supported by inference rather than substantial evidence. The only mention of alleged errors in the daily dispensing records was in the letter of admonition sent to the HMC, GE-26, which, standing alone, does not prove that the HMC's dispensing logs were errant. The Government has not entered evidence showing any specific defects in the HMC's dispensing logs, and has not entered copies of the HMC's dispensing logs to support its allegation. In fact, the evidence before me indicates that the HMC, up until the time of the 2006 inspection, kept meticulous daily dispensing records. GE-27; Tr. 626-28, 878. The Government failed to show, by a preponderance of the evidence, that the HMC failed to maintain daily dispensing records. Therefore, the Government's allegation to that effect is **NOT SUSTAINED**.

D. The 2011 Inspection

The Government alleged that, at the time of the 2011 inspection, the HMC had eight violations: (1) failing to provide records in a timely manner; (2) failing to conduct a biennial inventory; (3) failing to preserve 222 Forms for two years; (4) failing to maintain complete and accurate records of each controlled substance received;⁵⁹ (5) allowing an unauthorized person to sign 222 Forms; (6) failing to execute a power of attorney to allow an unauthorized person to sign 222 Forms; (7) failing to “completely and accurately complete” daily dispensing logs; and (8) failing to maintain adequate physical security of controlled substances. ALJ-1, at 2. I find that the Government showed, by a preponderance of the evidence, that the HMC committed the first, second, third, part of the fourth, and eighth violations.

There is significant disagreement between the parties over whether the HMC produced its records in a timely manner during the 2011 inspection. I find that the HMC did not produce these records “upon demand,” *Becker*, 77 Fed. Reg. at 72406, or within a “reasonable time,” *Chein*, 72 Fed. Reg. at 6593. The HMC had several days to locate the required documents and make them available for inspection, and still failed to do so. “To allow a registrant an even greater period of time to produce the records would create an incentive . . . to obstruct investigations by stalling for time in the hopes that DEA personnel would eventually give up and leave.” *Chein*, 72 Fed. Reg. at 6593.

The Respondent contends that it provided all required documents to the Case Agent, who refused to look at those documents for an unknown reason. ALJ-27, at 4-5. I do not find this position, supported by Mrs. Ozumba’s testimony, Tr. 722-23, 887, 890, 1012 (Dr. Ozumba), to be credible for three reasons. First, it makes little sense that DEA investigators would go to the HMC on two separate days to conduct an investigation, and on the second day come back into the HMC after having left, only to refuse to examine documents that Mrs. Ozumba claims were provided to the investigators. Second, the Case Agent credibly testified that the Ozumbas did not provide the necessary documentation, despite the DEA investigators’ attempts to work with the Ozumbas for over two hours. Third, Mrs. Ozumba felt it necessary to enter into a settlement

⁵⁹ The Government failed to distinguish between 222 Forms, discussed in the third allegation, and receipt records, discussed in the fourth allegation. Therefore, I consider the third allegation to address whether the 222 Forms were properly preserved and the fourth allegation to address whether the 222 Forms were properly completed.

agreement with the United States Attorney's Office when the HMC was civilly charged for its alleged recordkeeping violations. *See* Tr. 1055-57.

The Government attempts to establish liability on the part of the HMC through the use of the "Stipulated Agreement" Mrs. Ozumba signed on March 26, 2013. GE-7; ALJ-27, at 6-7. Based upon the results of the 2011 inspection, the DEA pursued a civil fine from the Respondent. Tr. 291. The United States Attorney's Office handled the case against the Respondent, which dealt solely with alleged recordkeeping violations. Tr. 1055. The HMC eventually negotiated a settlement with the United States Attorney's Office. Tr. 1056-57.

Federal Rule of Evidence 408 prohibits the use of a settlement agreement to prove or disprove the validity of a claim.⁶⁰ Fed. R. Evid. 408(a). "It is well-established that statements made for purposes of settlement negotiations are inadmissible, and Rule 408 of the Federal Rules of Evidence extends the exclusion to completed compromises when offered against the compromiser." *Playboy Enters., Inc. v. Chuckleberry Publ'g, Inc.*, 486 F. Supp. 414, 423 n.10 (S.D.N.Y. 1980) (citation omitted). Because settlement agreements may not be used to establish liability, the Government cannot rely on the Stipulated Agreement to prove that the Respondent committed recordkeeping violations in 2011. Moreover, even if Federal Rule of Evidence 408 did not apply, the Stipulated Agreement specified that it "does not constitute evidence or an admission by any person or entity, and shall not be construed as an admission by any person or entity, with respect to any issue of law or fact." GE-7, at 7.

Settlement agreements, however, may be admitted for a purpose other than to establish liability. Fed. R. Evid. 408(b); *see Manko v. United States*, 87 F.3d 50, 54-55 (2d Cir. 1996). Therefore, use of the Stipulated Agreement in this case has been limited to establishing that such an agreement existed between the HMC and the DEA and that the HMC knew of alleged recordkeeping violations found in 2011.

Mrs. Ozumba did not provide any of the HMC's records to the DEA on the first day of the inspection, and she did not provide any records for several hours on the second day of the inspection. Tr. 280-81. Even when Dr. Ozumba brought the keys to unlock the dosing room on day two, the HMC did not produce any 222 Forms from the audit period, even though the HMC should have had five 222 Forms. Tr. 306-14. The HMC also did not produce a biennial

⁶⁰ Although the Federal Rules of Evidence do not govern DEA administrative hearings, they can provide useful guidance "where they do not conflict with agency regulations." *Rosalind A. Cropper, M.D.*, 66 Fed. Reg. 41040, 41041 (2001) (citation omitted).

inventory. Tr. 477. During the inspection, the HMC was even unable to produce the records that the DEA needed to conduct an audit. Tr. 477. Considering these circumstances in their totality, I find that the HMC did not, at the time of the inspection, provide all of the required documents to the DEA investigators. Because the HMC was unable to produce some of its records over the course of several days during the 2011 inspection, the Government's allegation that the Respondent failed to provide records in a timely manner is **SUSTAINED**, and weighs in favor of revoking the Respondent's COR.

I also find that the HMC did not conduct a biennial inventory. Although the DEA investigators requested such an inventory from the HMC, the HMC did not provide one. Tr. 477. Because I find the Case Agent's testimony on this point to be credible for the reasons discussed *supra*, the Government's allegation that the Respondent did not conduct a biennial inventory is **SUSTAINED**, and weighs in favor of revoking the Respondent's COR.

The HMC did not produce any of its 222 Forms from the audit period upon the DEA investigators' request, even though the HMC should have had five 222 Forms from that period. Tr. 306-14; *see* GE-6, at 1-5. Because I find the Case Agent's testimony on this point to be credible for the reasons discussed *supra*, the Government's allegation that the Respondent did not preserve its 222 Forms is **SUSTAINED**, and weighs in favor of revoking the Respondent's COR. However, because the Respondent did not provide any 222 Forms, the Government cannot show that the HMC failed to properly complete such forms. Moreover, the Government did not enter any evidence demonstrating that the HMC failed to properly complete its receipt records. Therefore, the Government's allegation that the Respondent failed to properly complete 222 Forms is **NOT SUSTAINED**.

The Government was, however, able to obtain the Supplier's Copy of the HMC's 222 Forms from the audit period, which are presented in GE-6. Tr. 312-15. The signatures on these forms are not legible.⁶¹ The Government did not offer any evidence regarding whose signature appeared on the forms in GE-6. *See* Tr. 309. Moreover, it is unclear from the record whether Dr. Ozumba or Mrs. Ozumba had e-signature authority for the Respondent during the 2011 inspection's audit period. *See* Tr. 279. These were the only 222 Forms entered into evidence from the audit period. Because it is unclear who signed the forms, it is equally unclear whether

⁶¹ A layman's review of the signatures, however, finds them to share similarities with Mrs. Ozumba's signature. *Compare* GE-6, *with* GE-3, 27, 32, 33.

such person was authorized to sign 222 Forms. Therefore, the Government's allegations that the Respondent allowed an unauthorized person to sign 222 Forms, and failed to execute a power of attorney to allow such person to do so, are both **NOT SUSTAINED**.⁶²

The record indicates that the HMC did keep daily dispensing logs. Franks testified that she recorded into a computer file the amount of medication she dispensed each day, printed out that information, and put that information in a binder that was stored in the medication room. Tr. 163-71; *see, e.g.*, RE-G-H. Additionally, the record shows that the Respondent produced its dispensing logs to the DEA upon the investigators' request, but the Government did not introduce into evidence any of those logs concerning the one-year audit period. Tr. 291-92, 477, 751, 886.

The HMC offered evidence of the type of dispensing records it was maintaining around the time of the 2011 inspection. Respondent's Exhibit G contains the daily dispensing logs for methadone diskettes from October 1, 2011, to December 30, 2011. Tr. 852-53. Likewise, RE-H contains the daily dispensing logs for liquid methadone from October 14, 2011, to December 31, 2011. Tr. 854-55. Most of the records contained in RE-G are from outside of the 2011 inspection's audit period, and the records do not show the actual pharmaceutical name of the drug dispensed. Tr. 854, 920-24. Rather, they show that "DRT" tablets were dispensed, and they also record the strength in milligrams. RE-G. All of the records contained in RE-H are from outside of the 2011 inspection's audit period, and the records do not show the actual pharmaceutical name or strength of the drugs represented therein. Tr. 854, 920-24. Rather, they show that liquid "LMT" was dispensed and the dosage dispensed in milligrams. RE-H; Tr. 854, 923-24.

Here, the Government has failed to present substantial evidence to show that the HMC failed to "completely and accurately complete the daily dispensing logs." ALJ-1, at 2. In fact, the Government presented no documentary evidence from the audit period to document the alleged failure. At the hearing, the Government attempted to demonstrate shortcomings in RE-G and RE-H because they did not list the pharmaceutical name of the drugs dispensed or the strength. Tr. 920-24. I find the Government's questioning unconvincing for several reasons.

⁶² Importantly, Franks did testify that she was allowed to sign 222 Forms on behalf of the Respondent. Tr. 153. Franks did not testify as to when she was allowed to do so. However, the evidence shows that Franks signed several 222 Forms after the 2011 inspection. *See* RE-BB, at 1-6, 8; Tr. 155-57. Therefore, I find that Franks' testimony, standing alone, does not constitute substantial evidence that an unauthorized person was signing 222 Forms during the audit period of the 2011 inspection.

First, Mrs. Ozumba testified that RE-G and RE-H were not the only dosing sheets; they represent a general daily dispensing sheet, and the HMC also used an individualized sheet. Tr. 922. Second, there is no requirement in 21 C.F.R. § 1304.24(a) that the dispensing log specifically list the pharmaceutical name. Here, it is absolutely clear that the DEA investigators understood the terms DRT and LMT, and in fact, Mrs. Ozumba testified that she sometimes ordered liquid methadone using the term LMT. Tr. 919-20. Third, it is clear from the record that the HMC only ordered one strength of each form of methadone it used,⁶³ and the DEA investigators were well aware of that. Tr. 924-25. Finally, the strength of the dosage of the DRT is contained in the general dispensing sheets in RE-H, which lists the dosage in milligrams. *See, e.g.*, Tr. 917-18. Since the administrative record contains no dosing sheets for the audit period of the 2011 inspection, with the exception of pages one through eleven of RE-G, and since I find that those pages generally comply with the requirements of 21 C.F.R. § 1304.24(a), I find that the Government has not met its burden in demonstrating that the HMC failed to completely and accurately complete the daily dispensing logs. Therefore, the Government's allegation that the Respondent failed to "completely and accurately complete" daily dispensing records is **NOT SUSTAINED**.

Finally, concerning the 2011 inspection, the HMC's security system was not working properly at the time of the inspection because the security company did not receive signals from various security zones in the clinic. Tr. 288-89, 532-33. While the HMC corrected these security issues within a week of the inspection, Tr. 290-91, 533, 739-40, 901, the regulations require a narcotic treatment program's controlled substance safe to be "equipped with an alarm system which, upon attempted unauthorized entry, shall transmit a signal directly" to its security company. 21 C.F.R. § 1301.72(a)(1)(iii). The evidence shows that the HMC's system did not transmit this signal directly during the 2011 inspection. Therefore, the HMC's system did not comply with the requirements of 21 C.F.R. § 1301.72, and the Government's allegation that the Respondent failed to maintain adequate physical security of its controlled substances is **SUSTAINED**,⁶⁴ and weighs in favor of revoking the Respondent's COR.

⁶³ For methadone diskettes, the HMC ordered 40 mg, and for liquid methadone, the HMC ordered 1 mg/mL. Tr. 924-25.

⁶⁴ The Government discussed the fact that the HMC's dosing room did not have a panic button during the 2011 inspection. Tr. 289, 533. However, narcotic treatment programs are not required by federal regulations to have panic buttons in their dosing rooms. *See generally* 21 C.F.R. § 1301.72; *see also id.* § 1301.74(l); Tr. 601-02. Thus,

E. The 2014 Inspection

The Government alleged that, at the time of the 2014 inspection, the Respondent had committed eight violations: (1) failing to maintain complete and accurate records of controlled substances received, sold, and delivered; (2) failing to conduct a biennial inventory; (3) failing to conduct an inventory of buprenorphine; (4) failing to preserve 222 Forms for two years;⁶⁵ (5) failing to indicate the date of receipt of 222 Forms; (6) failing to execute a power of attorney authorizing an alternate person to sign 222 Forms; (7) failing to completely and accurately complete daily dispensing logs; and (8) having a variance in its controlled substance inventory. ALJ-1, at 3. I find that the Government showed, by a preponderance of the evidence, that the HMC committed the first, third, fourth, sixth, and eighth violations.

The Government entered into evidence a closing inventory and a computation chart from the 2014 inspection, which showed that the HMC had an overage of 1,200,050 dosage units of methadone diskettes, an overage of 500,251 dosage units of liquid methadone, a shortage of 30 buprenorphine 2 mg tablets, and a shortage of 175 buprenorphine 8 mg tablets. GE-9, 11; Tr. 375-80. I find that the closing inventory, computation chart, and the testimonies of McSwain and the Case Agent, when considered cumulatively, show that the HMC had variances in its controlled substances supply at the time of the 2014 inspection. By logical inference then, because the Respondent had a variance in its controlled substance supply, the Respondent's records were not accurate, particularly since the overages and shortages were calculated using the HMC's receipt records.⁶⁶ Tr. 379. Therefore, the Government's allegations that the Respondent failed to maintain complete and accurate records of controlled substances received, sold, and delivered, and that there was a variance in the HMC's controlled substance inventory, are **SUSTAINED**, and weigh in favor of revoking the Respondent's COR.

The Respondent did not provide the DEA with a biennial inventory. Tr. 329, 521. However, the Respondent provided the DEA with separate annual inventories for methadone

to the extent that the Government alleges that the HMC failed to maintain physical security of its controlled substances by not installing panic buttons in its dosing room, that allegation is **NOT SUSTAINED**.

⁶⁵ In its case, the Government failed to distinguish between receipt records, discussed in the first allegation, and 222 Forms, discussed in the fourth allegation. Therefore, I consider the first allegation to address whether the 222 Forms were properly completed, and the fourth allegation to address whether the 222 Forms were properly preserved.

⁶⁶ Unlike the Government's specific recordkeeping allegation concerning the 1997 inspection, the 2014 allegation concerning recordkeeping errors is a general allegation.

diskettes and liquid methadone, as well as for 2 mg and 8 mg buprenorphine. GE-10, at 1-4; Tr. 368-70, 584. Notably, the regulations require a registrant to inventory its controlled substances “*at least every two years.*” 21 C.F.R. § 1304.11(c) (emphasis added). If a registrant counts its controlled substances every day and records that count in a manner that satisfies the Code of Federal Regulations’ biennial inventory requirements, that daily inventory is considered to be an adequate biennial inventory. Tr. 246. Further, there is consistent credible testimony in the record that the dispensing nurses conducted a daily inventory of the controlled substances at the HMC. *See* Finding of Fact 4. Thus, the annual inventory provided to the DEA investigators would have been a sufficient inventory. The Government did not allege that the HMC’s inventory was inadequate; the Government only alleged that the HMC *failed to conduct* a biennial inventory. The HMC presented an inventory to the DEA investigators, and testimony supports that actual inventories were frequently conducted; therefore, the Government’s allegation that the Respondent failed to conduct a biennial inventory is **NOT SUSTAINED**.⁶⁷

The Government also alleged that the HMC failed to conduct an inventory of buprenorphine. The HMC did not produce an initial inventory for buprenorphine. Tr. 456. Rather, the Case Agent saw McSwain attempting to create a buprenorphine inventory, at Mrs. Ozumba’s direction, during the 2014 inspection to present to the DEA investigators. Tr. 92-94, 326. The Case Agent told McSwain to print off what she had without editing anything further. Tr. 326. These print-outs are pages three and four of GE-10. The Code of Federal Regulations, however, requires that an inventory of a controlled substance be taken on the date that a registrant “first engages in the . . . dispensing of controlled substances.” 21 C.F.R. § 1304.11(b). Comparing the timeframes reflected on pages three and four of GE-10 with the timeframes reflected on page one of RE-E, and the dates reflected in RE-AA, and considering McSwain’s and the Case Agent’s testimonies, I find that the buprenorphine “inventory” presented to the DEA investigators during the inspection was not made during an actual physical count of the HMC’s controlled substances and, therefore, was not an inventory under 21 C.F.R. § 1304.11(b). Therefore, the Government’s allegation that the Respondent failed to conduct an

⁶⁷ The Respondent also provided evidence that it created a monthly inventory generated from the daily dosing records. Tr. 114-15, 129. However, the record evidence indicates that this inventory did not involve an actual physical count of the Respondent’s controlled substances on hand. *See* Tr. 114-15, 129. For an inventory to satisfy the requirements of 21 C.F.R. § 1304.11, the inventory must record a count of “all controlled substances on hand on the date the inventory is taken.” 21 C.F.R. § 1304.11(a). The monthly “inventories” do not satisfy this requirement and are properly considered to be monthly summaries of the dispensing logs, rather than actual inventories under the regulations.

inventory of buprenorphine is **SUSTAINED**, and weighs in favor of revoking the Respondent's COR.

In the fourth allegation, the Government charged that the HMC failed "to preserve DEA 222 Order Forms." ALJ-1, at 3. In support of that allegation, the Government cited to 21 C.F.R. § 1305.17(a). *Id.* Nowhere prior to the hearing did the Government allege that the HMC failed to make its 222 Forms readily available for inspection. The HMC provided some 222 Forms from the 2014 audit period in response to the request of the DEA investigators. GE-13, at 1-4; Tr. 354-55; *see also* Tr. 89, 132-33, 1043. In conducting her audit, the Case Agent prepared a list of 222 Forms she had received from the HMC with a list of 222 Forms she obtained from the HMC's supplier. GE-16. On that list, the items in bold supposedly were not provided by the HMC to the DEA.⁶⁸ While the HMC provided additional 222 Forms to DEA after the date of the inspection, the DEA did not include them in its audit of the HMC because they were received after the completion of the audit. Tr. 354, 366-67. Nevertheless, there is one form that the Government identified, DEA Order form number 134110207, dated August 1, 2014, which the HMC has not produced. GE-16. Therefore, the Government's allegation to that effect is **SUSTAINED**, and weighs in favor of revoking the Respondent's COR.

The record also establishes that the HMC submitted an incomplete 222 Form, dated September 9, 2014, that failed to indicate the number of packages received or the date of receipt. GE-13, at 1; Tr. 354-55. However, the Government failed to submit evidence that the HMC actually received the ordered controlled substances and thereby failed to make a notation on the 222 Form.⁶⁹ Therefore, the Government's allegation to that effect is **NOT SUSTAINED**.

The Respondent also submitted a December 3, 2013 222 Form that bore Dr. Ozumba's signature, instead of Mrs. Ozumba's. GE-13, at 2; Tr. 355. The regulations permit only DEA registrants to issue orders for Schedule I and II controlled substances, unless a power of attorney

⁶⁸ The Case Agent's chart contains errors. For example, it reports that the DEA did not receive the 222 Form dated June 24, 2014, concerning liquid methadone and bearing DEA Order form number 134110205. GE-16. The DEA, however, obtained that form during its inspection on October 14, 2014, while at the HMC. GE-13, at 3. Other errors are also present on the Case Agent's document. She reports that DEA Order form numbers 130355192, 130355182, 130355184, and 134110205 were not provided by the HMC. GE-16. That information is wrong. *See* GE-14, at 4-7. *See also* RE-BB, at 24-27, for comparison.

⁶⁹ *See Superior Pharmacy*, 81 Fed. Reg. at 31338; *Hills Pharmacy*, 81 Fed. Reg. at 49842-43. The Government's exhibits do not contain information even from the supplier regarding whether the substances purchased through the (allegedly incomplete) September 9, 2014 222 Form were shipped. Government's Exhibit 15 includes a ship date of September 12, 2014, but the items shipped do not match those listed on the HMC's September 9, 2014 222 Form. *Compare* GE-13, at 1, *with* GE-15.

authorizing another person to do so has been properly executed. 21 C.F.R. §§ 1305.04(a), 1305.05(a). The power of attorney must be issued by the DEA registrant. 21 C.F.R. § 1305.05(a). The power of attorney must be retained with executed 222 Forms. *Id.* When Dr. Ozumba signed the 222 Form, Mrs. Ozumba was the DEA registrant for the HMC. Tr. 327. The DEA requested the HMC's power of attorney forms. Tr. 96, 1043. While McSwain knew that a power of attorney form had been prepared, she could not find it. Tr. 96. Ultimately, however, Dr. Ozumba provided the Case Agent with two power of attorney forms. Tr. 327-29, 389-92. The first form was a blank power of attorney that was prepared for Dr. Orette's signature, but Dr. Orette was not authorized to sign a power of attorney on behalf of the HMC because he was not the HMC's DEA registrant. GE-21; Tr. 390, 598-99. The second form was a new power of attorney signed on the day of the inspection, which was purportedly signed without any witnesses, with "C. Ozumba" written in as the grantor, no name written in as the "attorney-in-fact," and McSwain's name signed as the "person granting power." GE-20; Tr. 97, 328-29, 395-96. Even if this form had been properly executed, it did not authorize Dr. Ozumba to sign 222 Forms for Mrs. Ozumba, who was the registrant for the HMC. Therefore, the Government's allegation that the Respondent failed to execute a power of attorney to authorize an alternate person to sign 222 Forms is **SUSTAINED**, and weighs in favor of revoking the Respondent's COR.

Finally, the Government alleged that the HMC failed to completely and accurately complete daily dispensing logs for the controlled substances it dispensed. The record demonstrates that upon request, the HMC provided DEA with dispensing logs from October 1, 2013 through October 14, 2014 for methadone diskettes, and dispensing logs from September 30, 2013 through October 31, 2014 for liquid methadone. Tr. 105, 107, 135, 422, 456-57, 607, 847-48, 849-50, 915, 1043-44; *see* RE-A-B. Using the same rationale that I applied to a similar allegation regarding the 2011 inspection, I find that the Government has not met its burden of proof with respect to the dispensing records contained in RE-A-B. Therefore, the Government's allegation that the Respondent failed to completely and accurately complete daily dispensing logs for methadone diskettes and liquid methadone is **NOT SUSTAINED**.

With respect to the dispensing logs for buprenorphine, the HMC did not provide any during the inspection. In support of that allegation, the Government cited to 21 C.F.R. § 1304.24(a). ALJ-1, at 3. Nowhere prior to the hearing did the Government allege that the

HMC failed to make dispensing records readily available for inspection. At the hearing, the HMC provided for the first time the dispensing logs for buprenorphine. RE-AA; Tr. 461-62, 538. I find that those logs comply with the requirements of 21 C.F.R. § 1304.24(a). I further find that the HMC was not on notice that it would have to respond to a charge of failing to have its buprenorphine dispensing logs readily available for inspection. *CBS Wholesale Distribs.*, 74 Fed. Reg. 36746, 36749 (2009) (“One of the fundamental tenets of Due Process is that Agency must provide a Respondent with notice of those acts which the Agency intends to rely on in seeking the revocation of its registration” (citations omitted)). Therefore, the Government’s allegation that the Respondent failed to completely and accurately complete daily dispensing logs for buprenorphine is **NOT SUSTAINED**.

III. Notice of Misconduct

The Government alleged that the HMC was given several chances to comply with DEA registration requirements. First, the DEA issued a Letter of Admonition to the HMC on May 1, 1997, detailing the deficiencies noted during the April 1997 inspection. Second, the DEA and Mrs. Ozumba entered into an MOU on March 13, 2000, wherein she acknowledged the HMC’s violations from the December 6, 1999 inspection, and she agreed to comply with DEA requirements. Third, the DEA issued a Letter of Admonition to the HMC on September 26, 2006, based on the September 8 and 11, 2006 inspection. Fourth and finally, the HMC agreed to pay a \$10,000 penalty on April 3, 2013, to settle the DEA’s civil claims about violations discovered during the October 11 and 13, 2011 inspection, even though the Respondent denied culpability.

Past behavior is the best predictor of future behavior. *ALRA Labs., Inc. v. DEA*, 54 F.3d 450, 452 (7th Cir. 1995). A narcotic treatment program’s history of violations is relevant when evaluating whether revocation is appropriate. *Queens County*, 50 Fed. Reg. at 2099. For example, in *Berger*, the Agency revoked a narcotic treatment program’s registration because the program had ample notice of its recordkeeping violations and controlled substance variances and, yet, continued to be noncompliant. 52 Fed. Reg. at 17645-46. In that case, the DEA, over the course of eleven years, notified the registrant of its recordkeeping violations, discussed the violations with it, and gave it time to correct the violations. *Id.* The DEA found that the

registrant “consistently failed to maintain complete and accurate records,” even though it had “been given every opportunity by DEA to comply with the regulations.” *Id.* at 17645.

Here, the record shows that the HMC has had several opportunities to conform its behavior and recordkeeping to federal regulatory requirements and has consistently failed. Time and time again, the HMC was notified of its failings, but has yet to demonstrate that it can be a responsible registrant. While the Government has not proven each and every allegation set forth in the OSC, it need not do so. Rather, the law merely requires the Government to establish a noncompliance on the part of the Respondent with the standards respecting physical security and maintenance of records set forth by the Attorney General. As discussed *supra*, it has done so. Therefore, the preponderant evidence weighs in favor of the sanction sought by the Government.

IV. The Respondent’s Defenses

The Respondent argued in its prehearing statement that its significant and longstanding service to the community should be considered in evaluating whether its continued registration is appropriate. ALJ-6, at 3-4, 5; ALJ-14, at 5; Tr. 24-25. This argument fails for two reasons. First, the Respondent declined to present any community impact evidence at the hearing. Second, even if the Respondent had presented such evidence, community impact evidence is generally considered to be irrelevant to DEA revocation proceedings. *See, e.g., Linda Sue Cheek, M.D.*, 76 Fed. Reg. 66972, 66973 (2011) (noting that the DEA is not required to “consider community impact evidence”); *Bienvenido Tan, M.D.*, 76 Fed. Reg. 17673, 17694 n.58 (2011); *see also Holiday CVS, L.L.C.*, 77 Fed. Reg. 62316, 62339 (2012) (“Normal hardships to the practitioner and even to the surrounding community . . . are not relevant considerations.” (citations omitted)); *Mark De La Lama, P.A.*, 76 Fed. Reg. 20011, 20020 n.20 (2011) (declining to consider a registrant’s service to underserved and underinsured persons); *Steven M. Abbadessa, D.O.*, 74 Fed. Reg. 10077, 10078 (2009) (declining to consider the hardship imposed by the lack of a DEA registration).

The Respondent also argued that the amount of time that has passed since some of its violations mitigates its misconduct. ALJ-14, at 11-12. In most DEA cases, the mere amount of time that has passed since a Respondent’s misconduct is not a relevant consideration in weighing the public interest factors. *See, e.g., Tyson D. Quy, M.D.*, 78 Fed. Reg. 47412, 47418 (2013);

Leonardo V. Lopez, M.D., 54 Fed. Reg. 36915, 36916 (1989); *see also Robert G. Hallermeier, M.D.*, 62 Fed. Reg. 26818, 26821 (1997); *John Porter Richards, D.O.*, 61 Fed. Reg. 13878, 13879 (1996); *Norman Alpert, M.D.*, 58 Fed. Reg. 67420, 67421 (1993). However, narcotic treatment programs are evaluated under 21 U.S.C. § 823(g), which does not include a consideration of public interest factors, as discussed *supra*.

A narcotic treatment program's registration may be revoked based on *any* violation of any standard referred to in 21 U.S.C. § 823(g)(1). 21 U.S.C. § 824(a). Factors are not weighed, and conduct is not mitigated; the plain language of the Controlled Substances Act allows for revocation based on a single violation. Here, the Government has shown far more than one violation of federal regulations.

Although this is not a case in which public interest factors are weighed, it is a case wherein the Government seeks the revocation of a registrant's COR. Therefore, it is appropriate to apply standard considerations to that question. In that regard, once the Government presents a *prima facie* case for revocation, the burden of production shifts to the registrant to present "sufficient mitigating evidence" to show why it can be entrusted with a registration. 21 U.S.C. § 823(g)(1)(B) (connecting registration with a determination that there will be compliance with security and records maintenance requirements); *see Med. Shoppe—Jonesborough*, 73 Fed. Reg. at 387 (quoting *Samuel S. Jackson, D.D.S.*, 72 Fed. Reg. 23848, 23853 (2007)). To rebut the Government's *prima facie* case, a registrant must both accept responsibility for its actions and demonstrate that it will not engage in future misconduct. *Patrick W. Stodola, M.D.*, 74 Fed. Reg. 20727, 20734 (2009). The registrant may show acceptance of responsibility by providing evidence of remorse, efforts at rehabilitation, and recognition of the severity of its misconduct. *Robert A. Leslie, M.D.*, 68 Fed. Reg. 15227, 15228 (2003).

The registrant must accept responsibility and take remedial measures for each separate act of misconduct that it committed. *The Lawsons, Inc.*, 72 Fed. Reg. 74334, 74339 (2007); *see Jeffrey Patrick Gunderson, M.D.*, 61 Fed. Reg. 26208, 26211 (1996) (noting that a registrant must demonstrate remorse to the full extent of the documented misconduct). Acceptance of responsibility and remedial measures are assessed in the context of the "egregiousness of the violations and the [DEA's] interest in deterring similar misconduct by [the] Respondent in the future as well as on the part of others." *David A. Ruben, M.D.*, 78 Fed. Reg. 38363, 38364

(2013) (citation omitted). Here, the HMC must have accepted responsibility and taken adequate remedial measures regarding its recordkeeping and security violations.

In this case, Mrs. Ozumba has only taken responsibility for the allegations surrounding the 1997 inspection, and for being absent from the HMC during the 2014 inspection. Tr. 685, 687, 693, 929, 934. Applying the adage of “actions speak louder than words,” it would appear that the HMC has also accepted responsibility for the security violations that were identified in the 2011 inspection. Those security concerns were addressed within a week of the inspection, and the HMC was not cited for any security violations in the 2014 inspection. Tr. 290-91, 533, 739-40, 901. Were the security issues the only matter pending before me, I would find that the HMC had presented sufficient mitigating evidence to show why it could be entrusted with a registration.

Mrs. Ozumba testified that with respect to the 1999 and 2006 inspections, she considered the matters resolved based upon her responses to the DEA shortly after those inspections. Tr. 697-98, 690-92, 694. She also sent letters to the DEA after these inspections indicating steps she had taken to ensure further compliance with federal regulations. *See* GE-27, 37. In addition, in both the 2000 MOU and the 2013 Stipulated Agreement, the HMC agreed to comply with federal regulations governing the handling of controlled substances. *See* GE-7, 32. Unfortunately, there is no other evidence in the administrative record that supports a conclusion that the HMC’s prior violations were resolved, and the record does not support a conclusion that the terms of the MOU or the Stipulated Agreement have had any significant effect on the manner in which the HMC has maintained its records.

Of note, Mrs. Ozumba indicated that she had conducted training after the 2006 inspection, yet Bultron did not recall the HMC implementing any new policies, procedures or training after the 2006 inspection. GE-27; Tr. 239-40, 638. Mrs. Ozumba also testified that she had created a new form after the 2006 inspection, but her office manager, Garnett, testified that he created the form in 2012. Tr. 931-35, 964-77; *see also* RE-X. In fact, there has been little change in the HMC’s recordkeeping from 1997 through 2014. *See* Findings of Fact 1-5, 42. Furthermore, where a registrant has not accepted responsibility for its actions, remedial measures are not relevant. *See Hoxie v. DEA*, 419 F.3d 477, 483 (6th Cir. 2005) (recognizing the importance of admitting fault). As discussed *supra*, the HMC has not accepted responsibility for

its regulatory violations; therefore, any evidence of remedial measures is inconsequential. Therefore, the Respondent has failed to rebut the Government's *prima facie* case.

RECOMMENDATION

“One of the requirements for registration of a narcotic treatment program is that the program, comply with standards established by the Attorney General respecting . . . the maintenance of records (in accordance with section 827 of this title) on such drugs.” *Berger*, 52 Fed. Reg. at 17646 (internal quotation marks omitted). “The Administrator will not hesitate to revoke the registration of a n[a]rcotic treatment program that fails to meet its statutory and regulatory obligations to provide adequate security and recordkeeping.” *Queens County*, 50 Fed. Reg. at 2100.

The HMC has had a relatively long history of violating the Controlled Substances Act and its implementing regulations. More specifically, over the course of seventeen years and five inspections, the HMC has consistently failed to keep complete and accurate records concerning the receipt, accounting, and dispensing of narcotic substances and on one occasion was found to have inadequate security for its controlled substances. Even more troubling is the fact that, as discussed *supra*, the HMC has been warned on several occasions of its recordkeeping failings and has been provided multiple opportunities to correct them. Despite those efforts for compliance, the HMC has consistently failed.

“Diversion, and the potential diversion of methadone from narcotic treatment programs, is of grave concern to the Administrator. . . . The DEA regulation and supervision of these programs is intended to prevent the loss and diversion of methadone.” *Queens County*, 50 Fed. Reg. at 2099-2100. A respondent who “manifests a casual indifference to its obligation to provide adequate security, to keep complete and accurate records, and to properly account for its supply of narcotic drugs” is unfit to handle narcotic substances. *Id.* at 2100.

The record, as a whole, reveals a casual indifference on the part of the HMC to maintain adequate security and to keep complete and accurate records of its narcotic drug receipts, accounts, and dispensings. It also reflects that the HMC's past failures are likely to continue. “The integrity of the controlled substances distribution system, particularly where highly abusable, dangerous, and much sought-after drugs such as methadone are concerned, is too

important a consideration to be left to speculation.” *Metro Substance Abatement Program, Inc.*, 45 Fed. Reg. 78845, 78848 (1980). “To hope that the Respondent will operate responsibly in the future, in light of its well-documented past performance, would be speculative at best.” *Id.* The HMC’s consistent noncompliance with federal law despite having been afforded every opportunity to comply demonstrates that it cannot be entrusted with a registration. “The public should not be placed at the risk of . . . diversion any longer.” *Queens County*, 50 Fed. Reg. at 2100.

Therefore, I **RECOMMEND** that the Respondent’s DEA Certificate of Registration be **REVOKED** and any applications for renewal or modification of its registration be **DENIED**.

Dated: September 30, 2016

Charles Wm. Dorman
Administrative Law Judge

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